Attachment 1

Risk-Informed Regulation Implementation Plan

United States Nuclear Regulatory Commission
October 2000

FOREWORD

The Nuclear Regulatory Commission's (NRC's) policy for implementing risk-informed regulation was expressed in the 1995 policy statement on the use of probabilistic risk assessment (PRA) methods in nuclear regulatory activities. The policy statement says:

> The use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy.
>
> PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) should be used in regulatory matters, where practical within the bounds of the state-of-the-art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. Where appropriate, PRA should be used to support the proposal of additional regulatory requirements in accordance with 10 CFR 50.109 (Backfit Rule). Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed. It is, of course, understood that the intent of this policy is that existing rules and regulations shall be complied with unless these rules and regulations are revised.
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> PRA evaluations in support of regulatory decisions should be as realistic as practicable and appropriate supporting data should be publicly available for review.
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> The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgements on the need for proposing and backfitting new generic requirements on nuclear power plants licensees. The Commission also said -
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> Given the dissimilarities in the nature and consequences of the use of nuclear materials in reactors, industrial situations, waste disposal facilities, and medical applications, the Commission recognizes that a single approach for incorporating risk analyses into the regulatory process is not appropriate. However, PRA methods and insights will be broadly applied to ensure that the best use is made of available techniques to foster consistency in NRC risk-based decision-making.

In issuing the policy statement, the Commission said it expected that implementation of the policy statement would improve the regulatory process in three ways: by incorporating PRA insights in regulatory decisions, by conserving agency resources, and by reducing unnecessary burden on licensees.

In the March 1999 report "Nuclear Regulation-Strategy Needed to Regulate Safety Using Information on Risk" (GAO/RCED-99-95), the General Accounting Office made the following recommendation:

> To help ensure the safe operation of plants and the continued protection of public health and safety in a competitive environment, we recommend that the Commissioners of NRC direct the

> staff to develop a comprehensive strategy that includes but is not limited to objectives, goals, activities, and time frames for the transition to risk-informed regulation; specifies how the Commission expects to define the scope and implementation of risk-informed regulation; and identifies the manner in which it expects to continue the free exchange of operational information necessary to improve the quality and reliability of risk assessments.

In a January 2000 memorandum to the Commission, the staff outlined a strategy for risk-informed regulation. In March 2000, the staff gave the Commission an initial version of the Risk-Informed Regulation Implementation Plan (RIRIP). The Commission reviewed the plan and, after a March briefing by the staff, directed the staff in April 2000 to include in the next update of the implementation plan, an internal communications plan, training requirements for the staff, and a discussion of internal and external factors that may impede the transition. This version of the implementation plan is the first complete version. The purpose of this plan is to integrate the Commission's risk-informing activities. This version also includes the supplementary material the Commission asked for last April.

The staff intends to solicit internal and public comments on this version of the plan. These comments will be reflected in the next semiannual version, which the staff plans to finish in May 2001 following updates to Office operating plans.

Part I - The Nuclear Regulatory Commission's (NRC) Transition to Risk-Informed Regulation

1. Relevance to Strategic Plan

The NRC has for many years developed and adapted methods for doing probabilistic risk assessments (PRAs) and performance assessments (PAs) to better understand risks from licensed activities. The NRC has supported development of the science, the calculation tools, the experimental results, and the guidance necessary and sufficient to provide a basis for risk-informed regulation. By the mid-1990s, the NRC had a sufficient basis to support a broad range of regulatory activities. The Commission's 1995 PRA policy statement provides guidance on risk-informing regulatory activities. In this policy statement, the Commission said that "the use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy." This plan implements that policy.

In the policy statement, the Commission said it expected that implementation of the policy statement would improve the regulatory process in three ways: by incorporating PRA insights in regulatory decisions, by conserving agency resources, and by reducing unnecessary burden on licensees. The movement toward risk-informed regulation has indeed focused regulatory (and therefore licensee) attention on safety, reduced unnecessary regulatory burden, and made the regulatory process more effective and efficient. A collateral benefit is the opportunity to update the technical bases of the regulations to reflect advances in knowledge and methods and decades of operating experience. In line with the NRC's goal of increasing public confidence, the agency is implementing risk-informed regulation openly, giving the public and the nuclear industry clear and accurate information and a meaningful role in the process.

In 1998 the agency formally defined risk-informed regulation as an approach to regulatory decision-making that uses risk insights as well as traditional considerations to focus regulatory and licensee attention on design and operational issues commensurate with their importance to health and safety. A risk-informed approach enhances the traditional approach by (a) explicitly considering a broader range of safety challenges, (b) prioritizing these challenges on the basis of risk significance, operating experience, and/or engineering judgment, (c) considering a broader range of counter measures against these challenges, (d) explicitly identifying and quantifying uncertainties in analyses, and (e) testing the sensitivity of the results to key assumptions. A risk-informed regulatory approach can also be used to identify insufficient conservatism and provide a basis for additional requirements or regulatory actions.

While the PRA policy statement and other risk-informed regulatory initiatives were being developed, the NRC also developed a strategic plan for accomplishing its mission. The strategic plan sets strategic and performance goals and strategies for four strategic arenas: Nuclear Reactor Safety, Nuclear Materials Safety, Nuclear Waste Safety, and International Nuclear Safety Support. The agency has established four performance goals for the Nuclear Reactor Safety, Nuclear Materials Safety, and Nuclear Waste Safety arenas: (1) to maintain safety and protect the environment and the common defense and security, (2) to increase public confidence, (3) to make NRC activities and decisions more effective, efficient, and realistic, and (4) to reduce unnecessary regulatory burden. The strategic plan guides the agency's initiatives to support the transition to risk-informed regulation by defining strategic goals, performance goals and measures, and "strategies." The strategic plan strategies are general in nature. The RIRIP fills out some of the details, including –

- ongoing or planned activities to implement strategic plan strategies for risk-informed regulation
- draft criteria for risk-informing a program, practice, or requirement
- factors to consider in risk-informing a program, practice, or requirement
- relevance to performance-based regulation

The purpose of this plan is to integrate the Commission's risk-informing activities by identifying requirements and practices to be risk-informed and the necessary data, methods, guidance, and training. This plan is also intended to explain the agency's risk-informed regulatory policy to the public and the nuclear industry. The challenge in developing the RIRIP was to specify staff activities that are both necessary and sufficient to implement the strategic plan strategies. To show the relevance of the RIRIP to the strategic plan, the implementation activities and milestones in Part 2 of the RIRIP are described as implementing risk-informed regulatory strategies of the Strategic plan.

2. Guidelines for Selecting "Candidate" Requirements, Practices, and Processes

As the Federal agency responsible for regulating the civilian applications of nuclear technology, the NRC licenses a wide range of activities, including nuclear power generation, nuclear materials disposal, transportation and storage, nuclear materials processing and fabrication, and industrial and medical applications. The staff has developed draft screening criteria for identifying regulatory activities that could benefit from risk information. The screening criteria define the agency's policy on risk-informing regulations. Accordingly, they constitute the agency's overall strategy for implementing the 1995 policy statement. The staff will revise the criteria as it gains experience in apply them.

The draft screening criteria (65FR174) will help in assessing whether risk-informing a regulatory requirement or practice would –

- resolve a safety concern
- make the NRC (or Agreement States) regulatory process more efficient, effective or realistic
- reduce unnecessary regulatory burden on the applicant or licensee
- help to effectively communicate a regulatory decision or situation
- rely on existing risk data and analytical models (or data and models that could be developed)
- have a net benefit
- not encounter factors that would preclude changing the regulatory approach and therefore limit the utility of implementing a risk-informed approach.

Part 2 of the RIRIP tells how to apply the screening criteria. Results of the preliminary screening (described in the safety arena chapters in Part 2) will be incorporated in the agency's planning, budgeting, and performance management process.

3. Factors to Consider in the Transition to Risk-Informed Regulation

The NRC mission is to protect the public health and safety in civilian applications of nuclear technology. Historically, the agency has used an effective, albeit often conservative, approach for regulatory decisions. To accomplish its mission, the agency has established a regulatory system which presumes that the public health and safety are adequately protected when licensees comply with regulations and other license requirements. Regulations justified on the basis of adequate protection do not consider cost because they are required for safety, regardless of cost.

Since adequate protection is presumptively provided by existing regulations, the Commission has determined that, for nuclear power plants and fuel cycle facilities, proposed safety improvements beyond adequate protection should be adopted only if they provide "substantial" additional protection and the direct and indirect costs are justified. In the Nuclear Reactor Safety Arena, regulatory analysis guidelines and backfit analysis guidelines have been developed for assessing a "substantial" improvement and calculating cost-benefit. In the Nuclear Materials Safety Arena, the Commission has directed the staff to develop similar guidelines for fuel cycle facilities.

Risk-informed requirements must maintain reasonable assurance of adequate protection. A challenge in the transition to risk-informed regulation will be to maintain an acceptable level of safety while (1) improving efficiency, effectiveness, and realism in agency decisions, practices, and processes, (2) increasing public confidence in the agency, and (3) reducing unnecessary regulatory burden on licensees.

Since risk information is to be used to complement the traditional deterministic approach, risk-informed activities must preserve certain key factors of the deterministic approach. Among these factors are the fundamental safety principles of defense-in-depth, safety margins, the principle of "as low as reasonably achievable" (ALARA), radiation protection, and the agency's safety goals. The NRC has used these principles in its regulatory programs to maintain acceptable risk levels. They ensure that the nuclear industry is safe. In risk-informing its requirements and practices, the NRC must use these principles to complement risk information in ensuring that regulations focus on the issues important to safety and account for uncertainties affecting regulatory decisions[1]. Risk assessment insights will make regulatory decisions more effective and efficient and reflect realism.

For uniformity, the following factors should be considered in risk-informing an agency requirement or practice.

Defense-in-Depth

Traditionally, the NRC has required defenses to prevent radionuclide releases, to mitigate releases, and to limit human exposures to releases. Generally, defense-in-depth requires successive compensatory measures to prevent radiation exposures and to prevent accidents or

[1]The appendix discusses issues to consider in applying these principles in risk-informed regulation. Part 2 of the plan describes implementation activities to resolve the issues.

mitigate damage during a malfunction, an accident, or a natural event such as an earthquake or a tornado. In mechanical systems, defense-in-depth is assured by redundancy and diversity of power sources and physical separation of mitigation systems. Likewise, exposure to radiation is limited by shielding, distance, and time. In risk-informing a requirement or practice, the number and nature of physical and functional barriers for ensuring defense-in-depth should be commensurate with the risk and the uncertainty of the defenses.

In implementing risk-informed changes to requirements or practices, the staff should ask –
- Is defense-in-depth commensurate with the risk and uncertainty associated with the estimate of risk?
- Is a reasonable balance preserved among accident prevention, radiation exposure prevention, and consequence mitigation?
- Is there over-reliance on programmatic activities to compensate for design weaknesses?
- Is the redundancy, independence, and diversity of the system commensurate with the expected frequency and consequences of challenges to the system and with the uncertainties?
- Are defenses against potential common-cause failures preserved and have potential new common-cause failure mechanisms been assessed?
- Is the independence of barriers preserved?
- Are defenses against human errors preserved?

Safety Margins

Existing regulations were developed to ensure adequate safety margins to account for uncertainties in analyses and data and to ensure that adequate time is available to prevent the consequences of events. Safety margins are part of defense-in-depth; they assure safety in spite of uncertainties.

In implementing risk-informed changes to requirements or practices, the staff should ask –
- What safety margins are acceptable given the risk significance of the regulated activity and uncertainties?
- Is the proposed change consistent with the principle that sufficient, realistic safety margins be maintained?
- Is there a method for evaluating whether safety margins will be adequately maintained?

The ALARA Principle

Consistent with the linear hypothesis of radiation protection, which assumes a straight-line correlation between dose and somatic damage and does not allow for a threshold below which no injury will occur, licensees are expected to keep radiation releases as low as reasonably achievable (ALARA). Conservatism introduced by applying the ALARA principle compensates for uncertainties about the precise point at which no adverse health effects occur.

In implementing risk-informed changes to requirements or practices, the staff should ask –
- Is the risk-informed change consistent with the ALARA principle?
- If the ALARA principle is not used, how are limits set?

Safety Goals

The agency has developed quantitative safety goals for nuclear reactors to determine "how safe is safe enough?" The agency uses these goals as benchmarks for calculated risk measures. The Commission has directed the staff to develop materials safety goals similar to the NRC's reactor safety goals.

In risk-informing requirements or practices, the staff should ask:
- Does the practice provide a level of safety commensurate with the safety goal?

Other considerations for establishing quantitative safety goals are discussed in Appendix A.

Performance-Based Implementation

The agency has defined a performance-based requirement as one that relies upon measurable (or calculable) outcomes (i.e., performance results) to be met, while providing flexibility to the licensee as to the means of meeting these outcomes. SECY-00-0191 lists high-level guidelines that are intended to promote the use of a performance-based regulatory framework throughout the agency. In general, a performance-based regulatory approach focuses on results as the primary basis for regulatory decision-making and as such allows licensee flexibility in meeting a regulatory requirement. This in turn can result in a more efficient and effective regulatory process.

Having established the feasibility of the guidelines, the staff plans to develop implementing guidance to incorporate the guidelines into internal NRC procedures and to apply the guidelines to future regulatory initiatives, including those that are identified through risk-informed activities. Risk-informed regulation should incorporate performance measures whenever possible. Conversely, performance-based regulations should be risk-informed when possible. Figure 1 in the Appendix illustrates risk-informed and performance-based approaches.

In assessing performance-based implementation of risk-informed regulations, the staff should ask –
- Are there measurable or calculable parameters and criteria for judging the licensee's or the system's performance?
- Can the risk-informed change be made as a performance-based change?

Voluntary Alternatives versus Mandatory Requirements

The Commission has allowed reactor licensees to voluntarily implement risk-informed regulation. Thus, licensees may continue to operate under current requirements, or they may adopt a risk-informed approach. However, in risk-informing the agency's regulations, the staff may identify areas where mandatory requirements are warranted. The staff will evaluate proposed new requirements in line with existing guidance.

In considering voluntary versus mandatory implementation of risk-informed regulation, the staff should ask –

- Should all applicable licensees be required to implement the revised, risk-informed regulation?
- Should the regulation offer licensees alternative requirements?
- If staff practices are risk informed, are they mandatory or voluntary?

Selective Implementation

The issue is whether licensees that wish to use risk-informed options may selectively implement risk-informed requirements or must implement them all. Currently, selective implementation is decided on a case-by-case basis.

In weighing selective implementation of risk-informed changes to requirements or practices, the staff should ask –

- Are there acceptable methods for assessing the effect of selective implementation on safety?
- Would selective implementation decrease the agency's efficiency and effectiveness?
- In general, what limits, if any, should be placed on selective implementation?

Regulatory Oversight Process

The staff should follow the agency's regulatory oversight process in risk-informing requirements. Oversight can consist of inspection, assessment (e.g., through use of performance indicators), or enforcement. The staff should ask of every risk-informed regulation –

- Would licensee compliance with the risk-informed regulation be amenable to regulatory oversight?
- Would the risk-informed regulation increase the number or complexity of inspections needed to ensure compliance?
- Would the risk-informed regulation necessitate changes in the agency's oversight program?
- Would assessment or monitoring be required?

4. Communication Plans

The agency recognizes that it must keep its staff, the public, and the nuclear industry informed about its risk-informed regulatory activities. Part 2 of this plan lists milestones for soliciting input and feedback on certain regulatory initiatives in the Nuclear Reactor Safety, Nuclear Materials Safety, and Nuclear Waste Safety arenas. Part 3 describes the agency's plans for communicating the plan and obtaining input and feedback on it.

The staff guidance will be revised to incorporate advice on implementing risk-informed regulations (and performance-based regulations, as applicable) and explain the agency's PRA policy statement. For example, the management directive on the rulemaking process may be revised to describe the screening criteria for risk-informing regulations. Likewise, the charter of the agency's Committee for the Review of Generic Requirements (CRGR) may be revised to include reviewing criteria for risk-informing regulations.

5. Training Program

In the Nuclear Reactor Safety arena, the staff has already been given general training to increase its knowledge of and skills in probabilistic risk assessment. Additional training has been given on certain risk-informed regulatory initiatives, such as the training reactor inspectors were given on the revised reactor oversight process. In the Nuclear Materials Safety and Nuclear Waste Safety arenas, the NRC's Office of Human Resources is identifying, developing, and implementing staff training to ensure that the staff is fully prepared to effectively implement risk-informed regulation. Details of the agency's training program are given in Part 3 of this plan.

6. Success Measures

The performance goals in the NRC strategic plan use performance-based measures to determine whether the NRC is achieving its strategic goals. In 1999 the agency promised to include strategic and performance goals with performance-based measures in the performance plan and to describe how the agency programs and activities are linked to the strategic plan goals, measures, and strategies. Consequently, one function of the RIRIP is to identify risk-informed regulation milestones to be included in the performance plan. The staff is currently working to develop criteria for judging whether the transition to risk-informed regulation is proceeding in a successful manner but expects to develop the criteria by the end of calendar year 2000.

7. Organization of the RIRIP

Safety Arena Chapters

Part 2 of the plan describes the staff's activities for the risk-informed regulation transition. The activities are described as implementing strategic plan strategies. Thus Part 2 is organized like the Commission's strategic plan, with chapters on the Nuclear Reactor Safety arena, Nuclear Materials Safety arena, and Nuclear Waste Safety arena. Each chapter is organized around the strategic plan strategies relevant to risk-informed regulation in that arena. The implementation activities for each strategy are described, significant milestones are listed, and milestones schedules are noted. Progress in completing established milestones is also discussed. Tables 1 through 3 are summary lists of the implementation activities planned within each safety arena.

Certain implementation activities in the reactor safety, materials safety, and waste safety arenas may substantially differ in scope, form, and content. This is because the nature of the activities being regulated varies greatly, as does the availability of risk assessment methods. It should also be noted that this plan condenses the more detailed descriptions of staff activities in various Commission papers, program plans, and office operating plans.

Corporate Management Chapters

Part 3 of the plan describes the training program for giving the agency's staff the knowledge and skills needed to implement risk-informed regulation. Part 3 also describes the management strategies for ensuring effective communications among the NRC staff during the transition to risk-informed regulation.

Table 1. Nuclear Reactor Safety Arena Implementation Activities

Reactor Safety	Licensing	Regulatory Oversight
RSMS1-1	Oversight framework	Oversight framework
RSMS1-2		Inspection program
RSMS1-3		Performance indicators
RSMS1-4		Assessment process
RSMS1-5		Enforcement program
RSMS1-6		Improve oversight process
RSMS3-1		Risk-based performance indicators
RSMS3-2		Analyze performance indicators
RSMS3-3	Plant reliability studies	Plant reliability studies
RSMS3-4		Accident sequence precursors
RSMS3-5	System reliability studies	System reliability studies
RSMS3-6	IPEEE	IPEEE
RSMS5-1	Risk-informed licensing guidance	
RSMS8-1	RI Part 50 (Option 2)	
RSMS8-2	RI Part 50 (Option 3)	
RSMS8-3	Standard TS	
RSMS8-4	Fire protection	
RSMS8-5	Safeguards	
RSMS8-6	Reactor pressure vessel integrity	
RSEER1-1	Advanced reactors	
RSEER1-2	Standards	
RSEER1-3	Methods development	
RSEER1-4	Analytical tools	Analytical tools
RSEER1-5	International cooperation	International cooperation
RSEER1-6	Regulatory effectiveness	

Table 2. Nuclear Materials Safety Arena Implementation Activities

Materials Safety	Licensing	Regulatory Oversight
MSMS1-1	Identify and prioritize “candidate” regulations for risk-informing	Identify and prioritize candidates for RIR
MSMS1-2	Analyze Petition for Rulemaking (PRM) 36-1 (10 CFR 36.65 irradiator)	Revise inspection guidance for irradiators
MSMS1-3	Revise 10 CFR Part 35 (medical)	
MSMS1-4	Amend 10 CFR Part 70 PRM-70-7 (critical mass of special nuclear materials)	
MSMS1-5	Consolidate risk-informed on irradiators, limited scope, broad scope, radiopharmacy	
MSMS1-6		(1) Revise the nuclear fuel cycle facility safety inspection program (safety focus, baseline inspections) (2) Develop risk-informed enforcement actions for fuel cycle facilities
MSMS3-1		Streamline inspection and enforcement of materials licensees
MSEER1-1	Develop dose estimates to support Clearance Rule	Develop radiation protection standards and guidance for byproduct materials and guidance on sewer treatment facilities

Table 3. Nuclear Waste Safety Arena Implementation Activities

Waste Safety	Licensing	Regulatory Oversight
WSMS1-1	Study spent fuel cask responses to severe transportation accidents	Study spent fuel cask responses to severe transportation accidents
WSMS1-2	PRA of spent fuel dry storage cask	PRA of spent fuel dry storage cask
WSMS1-3	Risk-informed review of geologic repository for the disposal of spent nuclear fuel and high-level radioactive waste	
WSMS1-4	Revise 10 CFR 72.102 (graded approach to seismic design of dry cask storage)	
WSMS1-5	Reactor decommissioning rulemaking	
WSMS1-6	Risk-informed review of independent spent fuel storage installation	
WSMS1-7		Incorporate risk information into the decommissioning regulatory framework
WSMS4-1	Identify issues most important to repository safety	Identify issues most important to repository safety
WSMS4-2	Resolve issues most important to repository safety	Resolve issues most important to repository safety

Part 2: Risk-Informed Regulation Implementation Activities

Chapter 1. Reactor Safety Arena

Frank Miraglia, Arena Manager

1. INTRODUCTION

The NRC has generally regulated nuclear reactors based on deterministic approaches. Deterministic approaches to regulation consider a set of challenges to safety and determine how those challenges should be mitigated. As discussed in Part 1 and in the Commission's PRA Policy Statement, a probabilistic approach to regulation enhances and extends this traditional, deterministic approach by (1) allowing consideration of a broader set of potential challenges to safety, (2) providing a logical means for prioritizing these challenges based on risk significance, and (3) allowing consideration of a broader set of resources to defend against these challenges.

Until the accident at Three Mile Island (TMI) in 1979, the Atomic Energy Commission (now the NRC) only used probabilistic criteria in certain specialized areas of licensing reviews. For example, human-made hazards (e.g., nearby hazardous materials and aircraft) and natural hazards (e.g., tornadoes, floods, and earthquakes) were typically addressed in terms of probabilistic arguments and initiating frequencies to assess site suitability. The Standard Review Plan (NUREG-0800) for licensing reactors and some of the Regulatory Guides supporting NUREG-0800 provided review and evaluation guidance with respect to these probabilistic considerations.

The TMI accident substantially changed the character of the analysis of severe accidents worldwide. It led to a substantial research program on severe accident phenomenology. In addition, both major investigations of the accident (the Kemeny and Rogovin studies) recommended that PRA techniques be used more widely to augment the traditional nonprobabilistic methods of analyzing nuclear plant safety. In 1984, the NRC completed a study (NUREG-1050) that addressed the state-of-the-art in risk analysis techniques.

In early 1991, the NRC published NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants." In NUREG-1150, the NRC used improved PRA techniques to assess the risk associated with five nuclear power plants. This study was a significant turning point in the use of risk-based concepts in the regulatory process and enabled the Commission to greatly improve its methods for assessing containment performance after core damage and accident progression. The methods developed for and results from these studies provided a valuable foundation in quantitative risk techniques.

For the last several years, NRC's work to expand the use of PRA in regulatory processes has been documented in the PRA Implementation Plan (See SECY-99-211). Many of the early actions focused upon the development of skills, tools, and infrastructure for the application of risk information.

To understand the role to be played by the activities discussed in this risk-informed regulation implementation plan, it is necessary to recognize the significant accomplishments already completed. The staff's future actions build upon these activities and would not be possible without them. Thus, this chapter includes some information about recent activities, with the level of detail commensurate with their relationship to ongoing activities. For example, certain activities are currently being implemented, and thus the only action described in the plan is to monitor results and to seek out opportunities for improvement.

In considering what areas in the reactor safety arena to target for greater use of risk information, the NRC staff examined the sources of risk, the existing regulatory processes, and where there were the best opportunities for improvements. This led to a focus on reactors operating at power, but also gave consideration to (1) low power and shutdown conditions, (2) reactors undergoing decommissioning with fuel stored in pools (discussed under the nuclear waste arena), and (3) advanced reactor designs.

As discussed further in Part 1 and in the NRC's Strategic Plan (NUREG-1614), the NRC has developed goals, then planned strategies and activities to accomplish those goals. Within these strategies and activities, there are opportunities for greater use of risk information; however, much of the staff's activities in the reactor safety arena are not "risk-informed" as this is generally meant. For example, most licensing actions (i.e., many technical specification changes, license transfers, license renewals) do not require the use of risk information.

The evolution of the staff's application of risk information to the regulation of nuclear reactors is briefly discussed below. Detailed information on specific staff activities being undertaken to transition to risk-informed regulation, organized along the lines of the Commission's Strategic Plan, is provided in section 3 of this chapter.

One of the first examples are the Appendices in 10 CFR Part 52 certifying the evolutionary standardized reactor designs. Part 52 requires that a PRA be performed for any future design and also that the design meet certain technical requirements to prevent and mitigate severe accidents. A rulemaking in the planning stage would further require that operators of standard design plants maintain a "living" PRA.

SECY-97-171 (Consideration of Severe Accident Risk in NRC Regulatory Decisions) discussed how severe accident risk had been considered in the past as well as areas where it might be for the future. For instance, the NRC promulgated new rules requiring plants to deal with accidents that were beyond the normal design basis (station blackout and anticipated transients without scram) on the basis of risk information. The regulatory analysis guidelines by which NRC makes decisions about whether requirements are cost-beneficial backfits also consider risk of severe accidents. As discussed in Part 1, the development of the Safety Goal Policy was also a major step. Beginning in 1988, the staff also undertook a plan to consider severe accident risks for existing plants. This plan included several activities, including issuance of a Generic Letter (GL 88-20) asking licensees to conduct Individual Plant Examinations (IPEs) to look for plant-specific vulnerabilities to severe accidents. Other activities considered containment performance and utility severe accident management programs.

With the enhanced capabilities to assess risk, the staff also recognized that there were opportunities to reduce unnecessary regulatory burden. Stakeholder input was sought to identify areas that presented burden and in which risk information indicated that the burden may not be commensurate with the risks. Initial efforts focused on discrete areas to gain experience with use of the tools and guidance. As noted, the staff first developed the basic guiding principles (safety goal, PRA policy, and general guidance for licensing action decisions) and then proceeded with pilot applications. Over the last several years, the staff has reviewed individual licensing actions in such areas as graded quality assurance, in-service inspection, in-service testing, or changes to allowed outage times in the technical specifications. Having completed several pilots, the staff has concluded that greater use of risk information in the regulatory process could be accomplished in a manner that maintained safety, improved safety focus, and reduced unnecessary burden. Thus, the staff is now focusing upon other activities, such as rulemaking, to offer voluntary options for licensees. These activities include both specific technical areas (e.g., fire protection) as well as broader changes such as the adjustment of special treatment requirements.

It should be noted that, where necessary, the staff has also added requirements as a result of risk information. For example, the maintenance rule (10 CFR 50.65) was recently modified to require licensees to assess and manage the increase in risk that may result from maintenance activities.

Risk information is being used to focus staff activities with respect to inspection and enforcement and to adjust specific requirements on licensees. This was one of the drivers for the revised reactor oversight process and is discussed in detail in section 3.

The staff has also been using risk information for several years for event assessment. One example is the accident sequence precursor program that determines conditional core damage probability for particular events.

Finally, the staff is continuing activities to enhance its capabilities to conduct or review risk analyses through various research programs. These include activities to improve tools, enhance data, and to identify areas where requirements can be adjusted in a risk-informed manner.

2. RECENTLY-COMPLETED RISK-INFORMED INITIATIVES

Maintenance Risk Assessments and Risk Management

In 1991, the NRC issued a new rule, 10 CFR 50.65, that required licensees to monitor the effectiveness of maintenance activities. The rule arose out of recognition that balance of plant equipment failures can initiate transients that are potentially significant events and therefore that risk could be reduced by limiting failures of such equipment. Further, risk will be reduced if mitigating systems have high reliability and availability. The scope of equipment included within the monitoring requirements of this rule was intentionally broad to include many SSCs that are not classified as safety-related. In monitoring SSCs against performance goals, the guidance allows variances in the level of monitoring (e.g., at plant level, system level, or train level) based upon the importance of the system to safety. Thus, two significance categories (high safety-significant and low safety-significant) were developed, along with ranking methodologies.

Part of the 1991 rule stated that licensees *should* perform an assessment of the total plant equipment that is out of service to determine the overall effect on performance of safety systems. NRC later determined that this provision should be strengthened. On June 18, 1999, the NRC issued a final rule that requires licensees to assess and manage risk that may result from maintenance activities. As part of this rule, the Commission also determined that the scope of the assessment may be limited to structures, systems and components that a risk-informed evaluation process has shown to be significant to public health and safety. The NRC has endorsed an industry guidance document, through a Regulatory Guide, for implementation of this revised rule. The effective date of the revised requirements is November 28, 2000.

Alternative Source Term

Extensive research has led to an enhanced understanding of the timing, magnitude, and chemical form of fission product releases following nuclear accidents. The results of this work are summarized in NUREG-1465 which was published in February 1995. Application of this new knowledge to operating reactors can result in cost savings and simplification of operations without adverse impacts on public health and safety. In order to allow licensee use of the new source term as it is applied to design basis accident calculations (and resulting plant features and operations), the NRC has issued a rule (10 CFR 50.67) and associated guidance. In addition, the staff conducted pilot reviews at several plants. The final rule was published on December 23, 1999, and the final regulatory guide was published on July 28, 2000.

Licensee Reporting Requirements

The NRC conducted a rulemaking to revise requirements for licensee reporting of events and conditions with several objectives, including elimination of reports of no risk significance. Thus, reports of conditions “outside the design basis of the plant” have been eliminated, and instead the reporting criteria for such conditions focus upon whether there is a loss of function. Other risk-informed aspects of this rulemaking include the revised requirements for reporting of system actuations, by inclusion of a list of risk-significant systems. Such data supports NRC needs for risk studies about reliability and availability of systems. The final rule was approved by the Commission on July 11, 2000, and the rule will be published soon.

3. CURRENT INITIATIVES

This section presents the risk-informed implementation activities underway in the reactor safety arena. As discussed in Part 1, this section is organized along the lines of the Strategic Plan. That is, the activities are listed under the performance goal and strategy that they support. The table below lists the performance goals and the strategies that are supported by an activity. Note that many activities support more that one strategy. In such a case, the activity is discussed under the strategy that it primarily supports; however, the other strategies that it supports are also listed.

Maintain Safety

Strategy 1: *We will sharpen our focus on safety to include a transition to a revised NRC reactor oversight program for our inspection, assessment, and enforcement activities.*

RS-MS1-1	Oversight framework
RS-MS1-2	Inspection program
RS-MS1-3	Performance indicators
RS-MS1-4	Assessment process
RS-MS1-5	Enforcement
RS-MS1-6	Process improvements

Strategy 3: *We will evaluate operating experience and the results of risk assessments for safety implications*

RS-MS3-1	Risk-based performance indicators
RS-MS3-2	Performance indicator analysis
RS-MS3-3	Plant reliability studies (Sequence Coding and Search System)
RS-MS3-4	Accident sequence precursor program
RS-MS3-5	System reliability studies
RS-MS3-6	Individual plant examinations for external events (IPEEE)

Strategy 5: *We will ensure that changes to operating licenses and exemptions to regulations maintain safety and meet regulatory requirements*

RS-MS5-1	Risk-informed licensing guidance (1) RG 1.174 (2) Application-specific guidance .1 Graded quality assurance .2 In-service inspection .3 In-service testing .4 Technical specifications (3) Guidance for non-risk-informed licensing applications (4) Guidance for reviewing risk-important human actions

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less-prescriptive regulatory approaches to maintain safety*

RS-MS8-1	RIP50 (Option 2)
RS-MS8-2	RIP50 (Option 3)
RS-MS8-3	Standard technical specifications
RS-MS8-4	Fire protection
RS-MS8-5	Safeguards
RS-MS8-6	Reactor pressure vessel integrity

Efficiency, Effectiveness and Realism

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions*

RS-EE1-1	Advanced reactors
RS-EE1-2	Standards
RS-EE1-3	Methods
RS-EE1-4	Analytical tools
RS-EE1-5	International cooperation
RS-EE1-6	Regulatory effectiveness
RS-EE1-7	See standard technical specifications (MS8-3)

Reduce Unnecessary Regulatory Burden (UB)

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden*

RS-UB1-1	See Option 2 (MS8-1)
RS-UB1-2	See Option 3 (MS8-2)
RS-UB1-3	See licensing guidance (MS5-1)
RS-UB1-4	See Standard TS (MS8-3)

Strategy 3: *We will improve our reactor oversight process by redirecting resources from those areas less important to safety*

RS-UB3-1 (to 3-6)	See oversight process (MS1-1)

Performance Goal: Maintain safety, protection of the environment, and the common defense and security

Strategy 1: *We will sharpen our focus on safety to include a transition to a revised NRC reactor oversight program for our inspection, assessment, and enforcement activities.*

Performance Goal: Reduce unnecessary regulatory burden on stakeholders

Strategy 3: *We will improve our reactor oversight program by redirecting resources from those areas less important to safety.*

The NRC decided to revamp its inspection, assessment, and enforcement processes in response to a number of considerations, including improvements in the performance of the nuclear industry, the desire by NRC to apply more objective, timely, safety-significant criteria in assessing performance, and for efficiencies in implementation. This involved a number of related individual activities.

Implementation Activity MS1-1 (UB3-1): Establishment of a framework for deciding on inspection, assessment and enforcement actions for nuclear power reactors that focuses on activities and systems that are risk-significant. **(NRR)**

Implementation Activity MS1-2 (UB3-2): Establishment of a revised baseline inspection program for all nuclear power plants with additional inspections that may be performed in response to a specific event or problem at a plant. **(NRR)**

Implementation Activity MS1-3 (UB3-3): Establishment of performance indicators, to be submitted by licensees and used to monitor performance **(NRR)**

Implementation Activity MS1-4 (UB3-4): Establishment of an assessment process for determining NRC actions based upon indicator and inspection information. **(NRR)**

Implementation Activity MS1-5 (UB3-5): Revisions to the enforcement policy to integrate with the overall assessment process. **(OE and NRR)**

Implementation Activity MS 1-6 (UB3-6): Providing technical support to enhancements to the risk-informed reactor oversight process. **(RES and NRR)**

The basic approach under the new oversight process is to monitor performance with respect to reactor safety cornerstones (initiating events, mitigation system performance, barrier integrity, and emergency preparedness), radiation safety (worker exposure and general public protection during routine operations), and security. Indicators that can be used to monitor performance against these cornerstones have been developed. NRC has also identified "inspectable areas" which relate to these cornerstones and for which performance indicators alone are not sufficient to monitor performance (NRC is also inspecting the performance indicator reporting process).

The risk-informed oversight effort was developed using the results of research work and previous risk studies to identify the most significant systems, structures and components (risk matrices) and to develop processes by which the risk significance of inspection findings could be determined (significance determination process). For instance, in judging the areas and the amount of inspection effort to apply, the risk significance of the activities or systems involved was considered. Further, risk information was used where possible in setting the thresholds for the performance indicators. When judging the importance of inspection findings, the significance determination process uses risk information to assess the significance of the issue. These assessments are then input to an assessment process (action matrix) to define the agency response, depending upon both the significance of individual findings as well as overall cornerstone performance. The notebooks used for the SDP will be updated as needed to support implementation of the program.

Performance is then assessed by categorizing the indicators and inspection findings using significance thresholds to decide upon agency response. Depending upon the results in the various cornerstone areas, NRC will continue its baseline inspection, will inspect licensee corrective actions to deal with problem areas, will undertake additional inspections to focus upon the cause of the degraded performance, or if performance is unacceptable, the plant will not be permitted to operate until the problems are corrected.

The enforcement program changes have being integrated with the assessment process. For violations of low significance, the matter will be discussed in the inspection report, with no formal enforcement action. The licensee will place the issue in its corrective action program. For more significant issues, a Notice of Violation may be issued, with the assessment process being used to establish the appropriate response. Certain types of violations will continue to use the previous enforcement policy with use of severity levels and possible civil penalties. (See May 1, 2000 FR notice for details of the revised enforcement policy.)

Performance indicator information, inspection findings, and the results of the NRC assessment process are made publicly available through the NRC web site. The uniform use of this process allows for enhanced communication with licensees and the public.

The revised process reflected in the above noted activities were developed with input from a wide range of stakeholders. The new processes were piloted with a subset of the reactors, and the new program was implemented nationwide in April 2000.

The NRC has convened a task group to assess inspector training and qualifications in light of the new reactor oversight program and other risk-informed initiatives. The task group consists of representatives from NRR, HR and the regions. The task group began meeting in July and August to plan its review.

The activities now underway include full implementation of the oversight program at all power reactors, a lessons-learned review, and study of possible enhancements particularly for certain cross-cutting issues, like corrective action.

Major Milestones

Generate analytic tool or method to support periodic inspection of licensee's corrective action program 12/2000

Complete report on assessment of the extent to which human performance is reflected in the reactor oversight process 12/2000

Report on lessons-learned from full implementation 6/2001

Maintain and update significant determination process (SDP) notebooks, rev.2 . . . . 9/2001
of the revised oversight program

Performance Goal: Maintain safety, protection of the environment, and the common defense and security

Strategy 3: *We will evaluate operating experience and the results of risk assessments for safety implications.*

Implementation Activity MS3-1: Develop and implement risk-based performance indicators (RBPIs) **(RES and NRR)**

The reactor oversight process uses performance indicators and findings from risk-informed inspections to assess plant performance relative to the "cornerstones of safety." Risk-based performance indicators (RBPIs) will assess performance in three cornerstones of safety -- initiating events, mitigating systems, and containment barrier integrity. The RBPIs will address quantitative measures of performance in areas whose influence on core damage frequency and on containment performance is explicit. RBPIs will reflect significant changes in these performance parameters for a broad set of systems and operational aspects associated with licensee performance under the cornerstones of safety. As discussed in SECY-99-007 and SECY-99-007A, the RBPIs will enhance the reactor oversight process as summarized below:

- Reliability indicators will be developed at the component/train/system level;
- Indicators for shutdown modes and fire events will be developed consistent with the current state-of-the-art models, data, and methods for these areas;
- RBPI threshold values will be more plant-specific to reflect risk-significant differences in plant designs;
- An indicator will be developed to consistently assess the integrated risk significance of performance indicators and inspection findings on overall plant performance and will provide an additional input to the Action Matrix;
- Trending of risk-significant performance at the industry-wide level, including insights and identification of key contributors to any observed trends, will be provided where there are insufficient data or models to develop a plant-specific indicator.

Major Milestones

Issue Phase 1 RBPI development progress report for external stakeholder comment 1/2001

Brief ACRS on Phase 1 RBPI development progress 5/2001

Brief Commission on Phase 1 RBPI development progress 8/2001

Brief Commission on Phase 2 RBPI development progress 4/2003

Performance Goal: Maintain safety, protection of the environment, and the common defense and security

Strategy 3: *We will evaluate operating experience and the results of risk assessments for safety implications.*

Implementation Activity MS3-2: Maintain and disseminate performance indicator information. **(RES)**

The staff will continue to evaluate operational data to identify adverse safety trends and individual plants with marginal performance. This evaluation provides a scrutable process for identifying and predicting changes in safety performance and for conducting effective plant safety assessments.

Major Milestones

Issue FY2000 performance indicators in support of performance plan 1/2001

Performance Goal: Maintain safety, protection of the environment, and the common defense and security

Strategy 3: *We will evaluate operating experience and the results of risk assessments for safety implications.*

Implementation Activity MS3-3: Assess nuclear power plant equipment reliability and availability. **(RES)**

The NRC operates and maintains the Sequence Coding and Search System (SCSS) which contains information about events at nuclear power plants in a computer-searchable framework. This effort entails (1) coding an estimated 1100 licensee event reports (LERs) into SCSS each year; (2) maintaining the availability to the NRC staff and public of more than 45,000 LERs that are searchable from more than 150 fields on a user-friendly internet web site, which permits the NRC staff to perform more than 5,000 searches of this resource each year; (3) responding to approximately 200 requests for special searches, source documents, consultation, and inquiries involving SCSS data from the NRC; and (4) responding to approximately 1 high-priority, quick-turnaround technical assistance task involving SCSS data each year. The SCSS provides important access to information about events at nuclear power plants which is used to support agency evaluations and decisions.

The NRC also operates and maintains the Common-Cause Failure (CCF) database. Common-cause failures have the potential to adversely impact the safety of nuclear power plants and are significant contributors to plant risk. It is important, therefore, that operating events at power reactors be reviewed to disclose risk-significant interactions, phenomena, and behavior in the design and operating of power reactors that were not previously recognized or analyzed. Operation and maintenance of the CCF database involves (1) updating the CCF component data and parameter estimations for approximately 40 safety-system components using licensee event report (LER) data and nuclear power industry's Equipment Performance Information Exchange (EPIX) data; (2) issuing reports on CCF insights; and (3) supporting the international exchange of common-cause failure data.

These operational data will provide information on relevant operating experience that will be used to enhance plant inspections of risk-important systems. In addition, the data will be used by the NRC staff to perform technical reviews of proposed license amendments, including risk-informed applications. The data will also be used in the development of risk-based performance indicators to support improvements in the reactor oversight process.

Major Milestones

Continue to operate and maintain the Sequence Coding and Search System (SCSS) during FY2001 . . . . 9/2001

Continue to operate and maintain the Common-Cause Failure (CCF) database during FY2001 . . . . 9/2001

Continue to operate and update the agency's Reliability and Availability Database System (RADS) with new EPIX data as it is received from the Institute for Nuclear Power Operations (INPO) 9/2001

Performance Goal: Maintain safety, protection of the environment, and the common defense and security

Strategy 3: *We will evaluate operating experience and the results of risk assessments for safety implications.*

Implementation Activity MS3-4: Produce accident sequence precursor analyses. **(RES)**

The Accident Sequence Precursor (ASP) program provides analyses of the risk significance of operating experience on a plant-specific basis. It also provides trending information on industry and group-specific risk performance. Thus, the ASP program provides a risk perspective of nuclear power plant events to inform agency response and regulatory decisions. The staff will continue to review LERs, inspection reports and other sources to identify events that should be analyzed and will continue to produce an annual report of ASP results.

The staff plans to develop an enhanced capability to use expert opinion, human performance analysis, and state-of-the-art engineering analysis (such as thermal-hydraulic calculations) to improve the realism and consistency of ASP analyses. The staff also plans to improve the efficiency of the selection process for event/condition analyses using the results of the reactor oversight program's "significance determination process" results, inspection findings, and initial event assessment analyses. The planned improvements are expected to reduce the resources needed for screening events and improve the timeliness of final analyses. The staff also plans to improve its capability to derive ASP insights to make a more direct impact on the regulatory process. An eventual goal is to expand the number of staff capable of conducting ASP event assessments using state-of-the-art SPAR models.

Major Milestones

Provide 1999 annual report 3/2001

Performance Goal: Maintain safety, protection of the environment, and the common defense and security

Strategy 3: *We will evaluate operating experience and the results of risk assessments for safety implications.*

Implementation Activity MS3-5: Complete system reliability and related studies. **(RES)**

The staff will continue to conduct assessments of the risk significance of operational events and data trends from reactor operations. Trends in a) initiating events, b) system reliability and availability, c) non-compliance with license requirements, d) occurrences of common-cause failure modes, and e) events occurring at low power and shutdown conditions are assessed in conjunction with current PRAs so that safety vulnerabilities can be identified on a timely basis. These assessments also provide the information needed to update PRA assumptions to improve the accuracy and credibility of risk assessments.

Major Milestones

Complete study on CCF insights 1/2001

Complete system reliability and related studies
(air-operated valves, motor-operated valves, B&W reactor
pump seal, CE reactor pump seal) 2/2001

Performance Goal: Maintain safety, protection of the environment, and the common defense and security

Strategy 3: *We will evaluate operating experience and the results of risk assessments for safety implications.*

Implementation Activity MS3-6: Review IPEEE submittals and issue insights report. **(RES)**

The results of the licensees' individual plant evaluation (external events), IPEEEs, provide valuable information on the strengths and weaknesses of existing plants. The staff will complete its review of these evaluations and develop risk insights. The results of this effort will be used to support development of guidance and standards on the use of risk assessment and plant-specific risk information to support the risk-informed reactor oversight program. The outcomes of this work are potential safety enhancements and licensee burden reductions through greater use of risk analysis methods and results.

Major Milestones

Complete review of IPEEE submittals (discussed in Attachment 2) 1/2001

Issue draft report for public comments on general perspectives from IPEEE program 4/2001

Issue final IPEEE insights report 10/2001

Complete draft NUREG report on fracture testing of IAEA RPV material from cooperative program 9/2001

Finalize draft of RG 1.99 revision and publish for comment 12/2001

Publish a NUREG/CR report describing a generic flaw density and size distribution 12/2001

Complete analyses and propose technical basis for revision of PTS rule 9/2002

Performance Goal: Maintain safety, protection of the environment, and of the common defense and security

Strategy 5: *We will ensure that changes to operating licenses and exemptions to regulations maintain safety and meet regulatory requirements.*

Performance Goal: Reduce unnecessary regulatory burden on Stakeholders

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

Implementation Activity MS5-1 (UB1-3) Establish guidance for risk-informed licensing basis changes. **(NRR&RES)**

Subactivity 1: Regulatory Guide 1.174 (and update) and SRP Chapter 19

The PRA policy statement encourages greater use of PRA in all regulatory activities. One major activity is using PRA to support decisions to modify an individual plant's licensing basis. The staff prepared guidance documents to guide such risk-informed changes to a plant's licensing basis, as in requests for technical specification changes. The guidance describes acceptable means for assessing the nature and impact of licensing basis changes when the change request is supported by risk information. In being risk-informed, rather than solely based upon risk information, the NRC is retaining certain principles such as consistency with the defense-in-depth philosophy and maintenance of sufficient safety margins. The RG (and the SRP) were issued for public comment before being issued.

NRC is conducting periodic reviews of these documents to identify any desired improvements. The first review, documented in a memo dated June 30, 1999, identified four topics for revision. The topics were (1) discussion of an ASME standard on PRA quality, (2) shutdown risk, (3) seismic margins method, and (4) clarification on fuel burnup and composition.

Subactivity 2: Application-specific guidance

In addition to the general guidance documents for risk-informed licensing basis changes, NRC also developed documents specific to particular topics for which there was interest in pursuing risk-informed changes. These include graded quality assurance, inservice inspection, inservice testing, and technical specifications.

2.1 Graded Quality Assurance (RG 1.176)
2.2 Inservice Inspection (RG 1.178 and SRP 3.9.8)
2.3 Inservice Testing (RG 1.175 and SRP 3.9.7)
2.4 Technical Specifications (RG 1.177 and SRP 16.1)

Implementation Activity 2.1 : Updating the Graded QA RG

The graded QA RG 1.176 was issued in August of 1998. A GQA program was approved for the South Texas Project in November of 1997. Because the RG was issued after the pilot application was approved, it reflects the lessons learned from the pilot review.

While implementing the GQA pilot application, STP determined that they will derive much less benefit than they had anticipated from application of GQA. In particular, according to the licensee, special requirements in other regulations require continued complex and costly controls on many SSCs regardless of the reduced QA requirements. Consequently, there have been no further applications to apply GQA. In July of 1999, STP submitted a request for exemptions from many of the special treatment requirements, including greater relief from quality assurance requirements than allowed by the GQA program. The staff is utilizing this exemption request within the ongoing effort to risk-inform the special treatment requirements of 10 CFR Part 50 (see item MS8-1).

Furthermore, a 10 CFR 50.54(a) rule change became effective April 26, 1999, that allows licensees to apply any QA program alternatives or exceptions that have been approved by the NRC staff for any other nuclear power plant (if the bases can be shown to be applicable at the plant making the change) without requesting prior staff review and approval.

Therefore, changes to RG 1.176 will be not be performed until further experience is gained with the effects of the 10 CFR 50.54(a) rule change on licensees' QA programs, and the staff's review of the STP exemption request in completed. Based upon the current projected review schedule for the STP exemption request, the staff anticipates that the effort to revise RG 1.176 would commence no sooner than the spring of 2001 and take approximately one year.

Implementation Activity 2.2: Review of Inservice Inspection Topical Reports

On June 11, 1998, the staff sent to the Commission SECY-98-139, which transmitted Regulatory Guide 1.178 and Standard Review Plan (SRP) Section 3.9.8 for trial use. These documents provide guidance to licensees and staff regarding risk-informed inservice inspection (RI-ISI) programs for piping systems.

The industry submitted topical reports with two different methods, one developed by Westinghouse Owners Group and the other by Electric Power Research Institute (EPRI), for incorporating risk insights into their RI-ISI programs.

The staff was reviewing three ASME Code Cases (N-560, N-577, and N-578) in parallel with the pilot plant submittals.

Since the issuance of SECY-98-139, the staff has completed reviews of RI-ISI programs from four pilot plants and approved the methodologies presented in the two industry topical reports. However, industry schedules for RI-ISI submittals slipped such that the pilot plant reviews could not be completed until August 1999. The industry submittal for one of the methodologies (EPRI Report) was done in October 1999. The three ASME code cases have recently been revised to incorporate lessons learned in the review and approval of the pilot plant submittals and industry methodologies.

In addition to the four pilot plant, the staff has approved three other risk-informed ISI submittals. Five more are currently under review. However, as expected, the pilot program and other reviews have identified areas where the industry wants to modify the original generic framework. The Westinghouse Owners Group has submitted an addendum to its RI-ISI topical report that proposes to incorporate augmented programs not covered by the methodology approved by the staff. Furthermore, both the Westinghouse Owners Group and EPRI are meeting with the staff to discuss the possibility of expanding the RI-ISI methodology to include augmented inspection programs such as high energy line break exclusion zone piping and components other than piping.

The staff believes that work to revise Regulatory Guide 1.178 and the SRP should not commence until further experience is acquired with the revised industry methodologies (expected to be evaluated by the end of December 2000) and the finalization of the three ASME Code Cases. Contingent upon completion ot these documents, the staff expects to finalize Regulatory Guide 1.178 and the SRP by the end of December 2001.

Implementation Activity 2.3: Inservice Testing

The guidance for inservice testing has been issued and a pilot application was completed in 1998. Several other applications, generally of limited scope, have been approved or are in the process of being reviewed. As with the other application guides, the staff plans to review its experience for possible revision of the guidance. Candidate areas, as discussed in August 30, 1999, memo include potential relaxation of performance monitoring and corrective actions for low safety-significant SSCs if common cause failure is not of risk significance.

This review is planned to begin after March 2001.

It should also be noted that the ASME has been developing a series of Code Cases aimed at incorporating risk insights into the ASME Code test requirements for pumps and valves. Once approved, it may be appropriate to adjust the guidance in the RG to reflect their issuance.

Implementation Activity 2.4: Technical Specifications

Plant-specific licensing actions using the risk-informed guidance on TS have been processed largely in the area of relaxations of allowed outage times for particular SSC.

The August 30, 1999, review of the guidance document identified one area for possible revision relating to the nexus of configuration risk management with the maintenance rule (50.65(a)(4)). The staff's activities related to risk-informing TS include several other initiatives discussed under another activity(see item MS8-3).

Subactivity 3: Guidance for use when reviewing non-risk-informed submittals

As Policy Issue 4 in SECY-98-300 (Options for Risk-Informed Revisions to 10CFR Part 50), the staff recommended developing additional guidance with respect to the use of risk-informed approaches in regulatory activities. This guidance would be used in deciding if undue risk may exist when all other regulatory requirements appear to be met. In the related Staff Requirements Memorandum (SRM), the Commission approved the recommendation and requested the staff to submit clarifying guidance for Commission approval.

SECY-99-246 (Proposed Guidelines for Applying Risk-Informed Decisionmaking in License Amendment Reviews) proposed interim guidance for applying risk-informed decisionmaking in the review of non-risk-informed license amendment requests. Central to the process is a determination as to whether the license amendment request, if granted, could create "special circumstances" under which plant operation may pose an undue risk to public health and safety even though all other regulatory requirements appear to be satisfied. In the related SRM, the Commission approved the use of this guidance on an interim basis while the staff proceeds to engage stakeholders and finalize the guidance, and directed the staff to inform the Commission if it determines (during the interim period) that a license amendment application meets the special circumstances standard. The interim guidance has been disseminated to industry via Regulatory Issue Summary 2000-7 (issued 3/28/00).

The NRC plans to formally issue the guidance as a new appendix to Chapter 19 of the Standard Review Plan. The appendix provides guidance to the NRC staff on the use of risk information in those rare instances where license amendment requests meet regulatory requirements but raise significant risk concerns due to some special circumstances associated with the request. The proposed appendix was published in the Federal Register for public comment on April 10, 2000. The NRC held a public meeting in Rockville, Maryland to discuss the appendix on May 16, 2000, prior to close of the comment period.

The proposed guidance has also been discussed with the Advisory Committee for Reactor Safeguards (ACRS) and the Committee to Review Generic Requirements (CRGR). The staff forwarded final guidance documents to the Commission on September 26, 2000, following resolution of public comments and final review by ACRS and CRGR. Should the Commission approve, the staff intends to issue a Regulatory Issue Summary announcing the final guidance.

Subactivity 4: Provide guidance for reviewing risk-important human actions in plant-specific licensing actions.

The staff has prepared a draft report that contains technical bases to develop risk-informed guidance and acceptance criteria for the review of licensee proposals affecting operator actions credited in safety analyses. The technical bases uses a graded approach, with actions of higher risk importance receiving more detailed NRC review than those of lesser significance.

Major Milestones

Issue final guidance for special circumstances for use of risk-information in non-risk-informed licensing actions 11/2000

Publish NUREG/CR on risk-important human actions 10/2000

Publish NUREG Guidance for reviewing risk-important human actions . . . . 3 months after ACRS/CRGR review

Complete revisions to RG 1.174 . . . . 8/2001

Complete update of application-specific guides . . . . following RG 1.174 update

Complete RG 1.178 and SRP on risk-informed ISI 12/2001

Performance Goal: Maintain safety, protection of the environment, and the common defense and security

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less-prescriptive regulatory approaches to maintain safety.*

Performance Goal: Reduce Unnecessary Regulatory Burden on stakeholders

Strategy 1; *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

Implementation Activity MS8-1 (UB1-1): Develop an alternative risk-informed approach to special treatment requirements in Part 50, that would vary the treatment applied to structures, systems and components (SSC) on the basis of their safety significance using a risk-informed categorization method. **(NRR)**

The 1995 policy statement on the NRC's expanded use of PRA states "the use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy."

The Commission's current regulatory framework is based largely upon prevention and mitigation of particular design-basis events (DBE) under specific assumptions. Those SSCs needed to withstand these DBE are then subject to regulatory requirements intended to provide a high degree of assurance that those SSCs will function under these design basis conditions. These requirements, now referred to as "special treatment requirements," include qualification, change control, documentation, reporting, maintenance, testing, surveillance and quality assurance requirements. While these requirements have been effective in maintaining safety, in some cases they also result in unnecessary regulatory burden, in that the requirements apply to all SSCs with this category regardless of their relative contribution to plant safety.

The agency is committed to risk informing 10 CFR Part 50. This effort consists of two parts: (1) making changes to the overall scope of systems, structures, and components (SSCs) covered by those section in Part 50 requiring special treatment (such as quality assurance, technical specifications, environmental qualification), and (2) making changes to specific requirements in the body of regulations. (These efforts are referred to as Option 2 and Option 3, respectively, in SECY-98-300). The staff has developed detailed plans for accomplishing these activities. These activities are described further in SECY-99-256 and SECY-00-194 for Option 2 SECY-99-264, and in SECY-00-086, and SECY-00-0198 for Option 3 .

Under Option 2, the NRC is developing alternative regulations in 10 CFR Part 50 (and other applicable parts) that would modify the requirements for special treatment to focus on those SSCs that have been identified as important to protect public health and safety by using a risk-informed categorization approach. The categorization process is to be performed as part of an integrated decision-making process which uses both risk insights and traditional engineering insights. SSCs that are significant contributors to plant safety would continue to be subjected to the full set of special treatment requirements. In some cases, SSCs that are significant contributors to plant safety (using risk insights), but which are not presently required to satisfy special treatment requirements will, under the rule, have to meet certain requirements to maintain availability and reliability. Other SSCs that are not significant contributors to plant safety, but which are currently subjected to special treatment requirements, would be subject to reduced or no requirements.

In SECY-98-300 and in SECY-99-256, the staff outlined that the proposed approach would enable licensees and NRC to focus their resources on SSCs that make a significant contribution to plant safety. Through revision of the special treatment requirements, the underlying design functional requirements are retained, but burden reduction is anticipated with reducing or removing special treatment requirements on a set of low-significant SSCs. This approach was viewed as being consistent with the PRA policy statement, available PRA technology, efficiency of NRC resources, and responsiveness to stakeholder concerns. Further, changes to operationally-oriented requirements were viewed as a better opportunity for using risk insights rather than changes to design requirements in that existing facilities are already designed and constructed.

An Advance Notice of Proposed Rulemaking (ANPR) was published in March 2000 to seek public input on this proposal. In SECY-00-194, dated September 7, 2000, the staff discussed the public comments on the ANPR, the staff's preliminary views on the comments, and a conceptual approach for implementing the rulemaking plan. The next step is to prepare a proposed rule for Commission review.

To support the rulemaking efforts, NEI has proposed to prepare a guideline document to describe the categorization and special treatment requirements to apply in conjunction with such a rule change. The staff is reviewing the categorization and treatment sections of the guideline document separately and provided initial comments on the categorization section to NEI in a letter dated September 26, 2000.

In addition, the categorization of SSCs needs to use a PRA of acceptable quality to appropriately categorize the SSCs as to their relative risk significance. The industry has developed a peer review process to apply to PRAs; NEI-00-02 presents the peer review process including the technical elements used to judge the PRAs. The NRC is also reviewing this document in the context of its use in support of this initiative and provided initial comments to NEI in a letter dated September 19, 2000.

The staff concluded that pilot activities would be useful to help refine the rule and guidance documents. The NSSS owners' groups are developing plans for pilot activities, focusing on a limited number of systems to test efficacy of the categorization and treatment guidelines, but have not yet provided details of their plans to the NRC.

The licensee for South Texas has submitted an exemption request that would allow them to apply the concepts underlying this rulemaking (categorization, removal of special treatment requirements) at their facility, by receiving exemptions to certain existing requirements that would prevent them from otherwise undertaking such a program. This review is considered to be a "proof-of-concept" prototype for the rulemaking. The experience from their efforts and the staff review are being coordinated with the rulemaking activities and guidance development.

Major Milestones

Rulemaking

Proposed Rule 8/2001
Final Rule 12/2002

South Texas Exemption

Draft Safety Evaluation 11/2000

Final Safety Evaluation 4/2001

Pilot reviews

Owners groups submittals/plans 1/2001

Staff review complete 6/2001

NEI Guidance review

Staff completes review of categorization/treatment/peer review guideline documents . . . 6/2001

Performance Goal: Maintain safety, protection of the environment, and of the common defense and security

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less-prescriptive regulatory approaches to maintain safety.*

Performance Goal: Reduce unnecessary regulatory burden on stakeholders

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden*.

Implementation Activity MS8-2 (UB1-2): Make changes to specific technical requirements in Part 50 using risk information. **(RES and NRR))**

The staff's work on Option 3 will focus on providing a better balance to the Part 50 technical requirements among those needed to provide defense in depth, to maintain appropriate safety margins, and to limit risk. This improved balance will be achieved by systematic consideration of the Part 50 requirements. The staff's approach to risk-informing Part 50 will necessitate a broad assessment of Part 50 requirements, rather than a review of individual regulations. As such, the staff's work may involve changing regulations in sets, rather than individually. That is, risk-informing Part 50 may involve relaxing requirements in some areas in combination with increasing requirements in other areas to achieve a better balance.

The Option 3 effort entails two phases. In Phase 1, the staff will study the ensemble of technical requirements contained in 10 CFR Part 50 and associated implementing documents to: (1) identify candidate changes to requirements and design basis accidents, (2) prioritize candidate changes to requirements and design basis accidents, and (3) identify recommended changes to requirements. The focus of the staff's work will be on providing a better balance to the Part 50 technical requirements among defense-in-depth, safety margin, and risk considerations. This work will result in a set of recommended changes to the requirements and priorities for implementation. During Phase 2, the technical bases for rule changes will be developed and rulemaking will be conducted.

In SECY-00-0198, the staff provided (1) a status report on its study of possible risk-informed changes to the technical requirements of 10 CFR Part 50, (2) recommendations for risk-informed changes to 10 CFR 50.44 ("Standards for Combustible Gas Control System in Light-Water-Cooled Power Reactors") that will both enhance safety and reduce unnecessary burden, (3) policy issues for Commission decision, and (4) an update to the framework that describes the approach, process and guidelines the staff will apply in reviewing, formulating, and recommending risk-informed alternatives to 10 CFR Part 50 technical requirements.

Major Milestones

Provide recommendations and feasibility report to Commission on other Part 50 changes (such as 10 CFR 50.46) 6/2001

Provide recommendations and feasibility of changes to other rules (e.g., reactivity insertion accidents . . . . TBD

Performance Goal: Maintain safety, protection of the environment, and of the common defense and security.

Strategy 8: *We will continue to develop and incrementally use risk-informed, and, where appropriate, performance-based regulatory approaches to maintain safety.*

Performance Goal: Make NRC activities and decisions more effective, efficient, and realistic.

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

Performance Goal: Reduce unnecessary regulatory burden on stakeholders

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

Implementation Activity MS8-3 (EE1-1 and UB1-4): Develop risk-informed improvements to the standard technical specifications (STS). **(NRR)**

Since the mid-1980's, the NRC has been reviewing and granting improvements to technical specifications that are based, at least in part, on probabilistic risk assessment (PRA) insights. In its final policy statement on technical specification improvements of July 22, 1993, the Commission stated that it expects that licensees will utilize any plant-specific PRA or risk survey in preparing their technical specification related submittals. The Commission reiterated this point when it issued the revision to 10 CFR 50.36, "Technical Specifications," in July 1995. In August 1995, the NRC adopted a final policy statement on the use of PRA methods in nuclear regulatory activities that encouraged greater use of PRA to improve safety decision making and regulatory efficiency. Since that time, the industry and the NRC have been pursuing increased use of PRA in developing improvements to technical specifications. Guidance documents have been prepared to assist in this regard and a number of specific changes have been implemented (see implementation activity MS5-1).

Consistent with the Commission's policy statements on technical specifications and the use of PRA, the NRC and the industry continue to develop risk-informed improvements to the current system of technical specifications. These improvements are intended to maintain or improve safety while reducing unnecessary burden and to bring technical specification requirements into congruence with the Commission's other risk-informed regulatory activities.

Proposals for risk-informed improvements to the STS are identified by the industry and discussed with the NRC staff before a submittal is developed. The proposals are judged based on their ability to maintain or improve safety, the amount of unnecessary burden reduction they will likely produce, their ability to make NRC's regulation of plant operations more efficient and effective, the amount of industry interest in the proposal, and the complexity of the proposed change.

The industry and the staff have identified eight initiatives to date for risk-informed improvements to the STS. They are:

1. Define the preferred end state for technical specification actions (usually Hot Shutdown for PWRs);
2. Increase the time allowed to delay entering required actions when a surveillance is missed;
3. Modify existing mode restraint logic to allow greater flexibility (i.e., use risk assessments for entry into higher mode limiting conditions for operation (LCOs) based on low risk);
4. Replace the current system of fixed completion times with reliance on a configuration risk management program (CRMP);
5. Optimize surveillance frequencies;
6. Modify LCO 3.0.3 actions to allow for a risk-informed evaluation to determine whether it is better to shut down or to continue to operate;
7. Define actions to be taken when equipment is not operable but is still functional.
8. Risk-inform the scope of the TS rule

Major Milestones

Staff completes review of Initiative 2 . . . . 12/2000

Industry submits proposal for Initiative 6 . . . . 1/2001

Staff completes review of Initiative 3 . . . . 3/2001

Industry submits proposal for Initiative 1 . . . . 3/2001

Staff completes review of Initiative 6 . . . . 7/2001

Staff completes review of Initiative 1 . . . . 9/2001

Industry submits proposals for Initiatives 4, 5, and 7 . . . . 12/2001

Staff completes review of Initiatives 4, 5, and 7 . . . . 12/2002

Industry submits proposal for Initiative 8 . . . . 12/2002

Staff completes review of Initiative 8 . . . . 12/2003

Performance Goal: Maintain Safety, protection of the environment, and of the common defense and security

Strategy 8 *We will continue to develop and incrementally use risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS8-4: Develop alternative fire protection standards for nuclear power plants. **(NRR&RES)**

The staff has been working with the National Fire Protection Association (NFPA) to develop an alternative performance-based risk-informed fire protection standard for nuclear power plants. A draft of this standard, NFPA-805,has been issued for public comment and resolution of comments is expected in the spring of 2001. A rulemaking plan was submitted to the Commission in SECY-00-0009 that would, after final Commission endorsement, provide for incorporation of that standard into Commission regulations as a voluntary alternative to current fire protection requirements.

Another activity related to fire protection is the Circuit Analysis Resolution Program. In response to the need to resolve post-fire safe shutdown, fire-induced circuit failure analysis issues, the Boiling Water Reactor Owners Group (BWROG) and the Nuclear Energy Institute (NEI) have respectively developed deterministic and risk-informed post-fire safe shutdown methodology documents. These two documents have recently been combined into one document which provides a step-by-step means of deterministically conducting safe shutdown analyses, while is intended to provide optional risk-informed methods for selected analytical steps.

Methodology improvements related to fire protection are discussed under item EE1-3.

Major Milestones

Publish proposed rule 10/2001

Final Rule 4/2002

Performance Goal: Maintain safety, protection of the environment, and of the common defense and security

Strategy 8 *We will continue to develop and incrementally use risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS8-5: Develop alternative requirements for safeguards that are risk-informed and/or performance-based. **(NRR)**

The staff has underway a comprehensive review of 10 CFR 73.55; the staff intends to include a requirement for power reactor licensees to conduct drills and exercises to evaluate their protective strategy against a simulated design basis threat. In performing this review, the staff is also seeking opportunities to make the requirements risk-informed, as for example in terms of the equipment that needs to be protected.

In SECY-00-0063, the staff provided its proposed approach for revising this regulation, which was approved by the Commission in an SRM dated April 12, 2000. Subsequently the staff provided a status report of its activities in SECY-00-0142, dated June 26, 2000.

Major Milestones

Proposed rule to Commission 5/2001

Performance Goal: Maintain safety, protection of the environment, and the common defense and security

Strategy 8: *We will continue to develop and incrementally use risk-informed, and where appropriate, performance-based regulatory approaches to maintain safety.*

Implementation Activity MS8-6: Develop the technical basis to improve evaluations of reactor pressure vessel (RPV) integrity. **(RES)**

The staff is working to develop the technical basis to improve the realism of evaluations of reactor pressure vessel (RPV) integrity to support risk-informed modifications to the regulations associated with RPV integrity. The staff is evaluating the application of advanced fracture mechanics concepts to the revision of the regulatory framework for RPV integrity to provide analysis codes and techniques for evaluating licensee submittals pertaining to RPV integrity, particularly as related to pressurized thermal shock (PTS). The staff is also conducting the research and analyses needed to develop a statistically valid generic flaw density and size distribution for reactor vessel welds and plates for use by the staff and licensees in performing probabilistic fracture evaluations of reactor pressure vessels. In addition, the staff is performing experimental program and computer analyses to support rulemaking for PTS and guidance for reactor vessel embrittlement. The results of these efforts will be reflected in review guidance documents and in modifications to the regulations addressing issues associated with reactor pressure vessel integrity such as setting operating pressure-temperature limits and LTOP setpoints, and in applying the 10 CFR 50.61 pressurized thermal shock (PTS) screening criteria. Some specific staff activities include:

-Continuing the mechanistic and statistical assessment of plant embrittlement data

-Completing a NUREG report on effects of heat treatment and chemistry unavailability on embrittlement trends

-Completing the development of the technical bases for revision of RG 1.99

-Completing irradiation of high-Cu, high-Ni welds and validation of embrittlement trend curves

-Conducting an expert elicitation to verify that a generalized flaw size and density distribution can be properly developed for the entire population of U.S. RPVs and to assist in developing a flaw distribution

-Performing calculations to provide technical basis for revising 10 CFR 50.61 (the PTS rule)

-Integrating results of probabilistic fracture calculations and PRA considerations to develop revised PTS screening criteria for incorporation into 10 CFR 50.61

-Characterizing flaw density size distributions for River Bend and Hope Creek vessels

Major Milestones:

Performance Goal: Make NRC activities and decisions more effective, efficient, and realistic.

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

Implementation Activity EER1-1: Incorporate risk insights into reviews of advanced reactor designs. **(NRR)**

As discussed in several Commission policy statements (e.g., Policy Statement on Severe Reactor Accidents regarding future designs and existing plants August 1985), and SECY papers, for advanced reactors, the Commission's objective is that designers of new plants would achieve a higher standard of severe accident performance than prior designs.

In the requirements promulgated in 10 CFR Part 52 for Standard Design Certification applications, NRC included a requirement that a PRA be performed for each design. Further, the application is to demonstrate compliance with technically-relevant requirements set forth in 50.34(f)[added as lessons-learned from the TMI accident]. The staff also assessed performance with respect to other technical and policy issues in SECY-90-016 and SECY-93-087. These issues were derived, in part, from risk insights. Embodied in the change control processes are specific criteria for when NRC review is needed for changes affecting resolution of severe accident issues.

Three standard design certifications are complete. The staff is performing a lessons-learned review of Part 52 based on these three reviews. As part of this effort, the staff also plans to add a requirement that an applicant/operator of a standard-design reactor would maintain, update and use the PRA ("living PRA") beyond the design phase for the life of the facility.

Major Milestones

Proposed revisions to Part 52 to Commission . . . . spring 2001

Final rule to Commission 2002

Performance Goal: Make NRC activities and decisions more effective, efficient, and realistic.

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

Implementation Activity EER1-2: Develop standards for the application of risk-informed, performance-based regulation in conjunction with national standards committees. **(RES and NRR)**

The increased use of probabilistic risk assessments (PRA) in the regulatory decision-making process requires consistency in the quality, scope, methodology and data used in such analyses. These requirements apply to PRAs developed by industry to support specific, risk-informed licensing actions as well as to PRAs developed by NRC staff to analyze specific technical issues or to support risk-informed Commission decisions. To this end, NRC has been working with the American Society of Mechanical Engineers (ASME) to develop a national consensus standard setting forth specific guidance regarding the construction and execution of a PRA covering internal initiating events (Level 1). When developed, such a standard will help to ensure that PRAs developed in accordance with this standard are robust, consistent, and defensible and are documents upon which regulatory decisions can confidently be made. While the ASME maintains overall responsibility for this effort, active NRC and industry participation has been, and will continue to be, essential to the development of such a standard. In parallel, the staff has been working with the National Fire Protection Association (NFPA) to develop standards for fire risk analysis (See activity MS8-4).

More recently, the NRC staff has been working with the American Nuclear Society (ANS) to develop a companion standard covering probabilistic analyses that would include the progression of severe accidents, the impacts of external events on plant risk, and risk-significant events that could occur when a plant is operating at low power or when shutdown (LP/SD).

As discussed under activity MS-8-1, the staff is also reviewing the NEI peer review process for PRA, in particular for use with that activity.

In addition, the staff is active with the Institute of Electrical and Electronic Engineers (IEEE) in developing an industry standard for conducting human reliability analysis at nuclear power generating stations.

Major Milestones

Recognizing that control of these projects properly rests with the standards committees, the following milestones have been established by these organizations:

Final PRA standard issued by ASME 3/2001

Final fire PRA standard issued by NFPA 3/2001

Final PRA standards issued by ANS
Seismic 6/2001

LP/SD 6/2001

Final HRA Standard issued by IEEE 1/2005

Performance Goal: Make NRC activities and decisions more effective, efficient, and realistic.

Strategy1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

Implementation Activity EER1-3: Develop improved methods for calculating risk in support of risk-informed regulatory decision making **(RES)**

From the ground-breaking work of the WASH-1400 study and the NUREG-1150 reactor risk studies through the individual plant examinations and present risk studies, tremendous advancements have been made in PRA methods. Consistent with the direction provided in the 1995 PRA policy statement, the NRC is continuing to develop methods needed to better support realistic, risk-informed decision making. Current PRA methods do not adequately address certain key aspects of plant risk, including the effects of quality assurance, human reliability, fire, low power and shutdown operations, degraded SSCs, and digital instrumentation and control failures. Uncertainty concerning the nature and magnitude of the contributions of these aspects to plant risk, particularly as they relate to agency decision making processes and acceptance criteria, will limit progress in risk-informed regulation by requiring conservative decisions to be made to account for large uncertainties. The new methods will complement the methods developed to-date, further reducing uncertainties and improving realism. The quality of risk assessments is also highly dependent upon the quality of the engineering analyses (e.g., thermal-hydraulic, severe accident, structural) that is used to calculate plant performance and success criteria. Although not included in this plan, work to improve and ensure the analytical tools used for these analyses are realistic and readily useable is vital to the success of risk-informed regulation.

Decisions to pursue development of methods and models are made based on three general considerations: (1) the importance of new methods to risk informing our regulations; (2) the adequacy of existing methods for understanding the risk implications of experimental findings and operational experience; and (3) the availability of methods for assessing the risk associated with the introduction of new technologies and new reactor designs. These criteria are associated with the issue of PRA model completeness and the degree to which PRA models adequately characterize risk-important failure modes and mechanisms. Thus, the more complete our understanding of plant risk, the more free are we to identify and remove unnecessary conservatism from our regulations and decision making.

With these three considerations in mind, the following research efforts have been identified:

- In the effort to risk inform Part 50 requirements, quality assurance requirements were identified as high-priority candidates to be risk informed. A study is being planned to assess the feasibility of modeling the influence of quality assurance activities on plant risk within the context of PRA. Dependent on the results of this study, future work may be pursued to develop such models.

- The development of performance-based fire standards and regulations requires a sound understanding of fire and its contribution to power plant risk. Current fire PRA models are not adequate to support credible, risk-informed changes to these standards and regulations.

A fire risk program has been developed and is being implemented to address the complex issues associated with fire risk.

- Level 2 PRA methods address containment performance. An evaluation of the implications of hydrogen research findings on the realism of existing level 2 PRA methods is underway and may suggest needed improvements.

- Regulatory Guide 1.174 provides guidance for making changes to a plant's licensing bases based on total plant risk. Plant risk during all plant operating modes has not yet been calculated, most notably during low power and shutdown operations. The consequences of incomplete risk profiles are that conservative decisions are made to compensate for the lack of risk information and uncertainty exists in our knowledge of defense-in-depth and safety margins during such operating modes. No research is underway at this time to calculate the risk associated with low power and shutdown operations.

Major Milestones

Issue report on fire suppression analysis methods 12/2000

Draft plan for HRA research 12/2000

Draft plan for digital system software risk 12/2000

Revised plan for fire risk 11/2000

Complete feasibility study on developing PRA models on QA effects 9/2001

Develop plan to upgrade MACCS on health effects, land contamination . . . . TBD

Performance Goal: Make NRC activities and decisions more effective, efficient, and realistic.

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

Implementation Activity EER1-4: Develop and maintain analytical tools for staff risk applications **(RES)**

The agency has developed analytical tools that the staff uses in its risk assessments associated with generic safety issues, regulatory backfit reviews, plant operating states, and operational experience. This suite of PRA codes has given the staff the tools it needs to reach risk-informed decisions, independent of licensee analyses. Thus, the staff plans to continue to maintain the SAPHIRE computer code for conducting PRA. The accident sequence precursor (ASP) program uses simplified PRA models as part of the staff's operating event assessments. The staff also plans to continue to develop and improve the ASP SPAR models so the staff can better analyze the risk significance of operating events.

Major Milestones

Complete third set of preliminary (level 1, revision 3) ASP SPAR models 9/2001

Continue SAPHIRE computer code data entry and maintenance 9/2001

Performance Goal: Make NRC activities and decisions more effective, efficient, and realistic.

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

Implementation Activity EER1-5: Organize and conduct an international cooperative research program on PRA to coordinate and share results of research activities. **(RES)**

Recognizing the increasing use worldwide of probabilistic risk assessment (PRA) and probabilistic safety assessment (PSA) in the regulation of nuclear facilities, there is a strong need to maximize progress in addressing key PRA/PSA research and development issues. As such, COOPRA (the International Cooperative PRA Research Program) was formed to:

- Improve the sharing of PRA/PSA information

- Improve efficiency in developing and using needed PRA/PSA tools.

Major Milestones

Convene annual international cooperative PRA program meeting 12/2000

Performance Goal: Make NRC activities and decisions more effective, efficient, and realistic

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

Implementation Activity EER1-6: Assess regulatory effectiveness using risk information. **(RES)**

The staff will conduct an integrated evaluation of risk information, inspection findings, operating experience, domestic and international research results, and cost data to identify ways to improve the effectiveness of NRC regulatory requirements, guidance, and processes.

Major Milestones:

Evaluate effectiveness of ATWS rule 4/2001

Evaluate effectiveness of USI A-45 resolution 9/2001

Evaluate effectiveness of 10CFR50, App J, Option B 1/2002

Part 2: Risk-Informed Regulation Implementation Activities

Chapter 2. Nuclear Materials Safety

Carl Paperiello, Arena Manager

In the past, the Office of Nuclear Material Safety and Safeguards (NMSS) has used risk information in making regulatory decisions on a case-by-case basis. Because of the varied nature of the activities in the arenas within NMSS, a single approach, such as probabilistic risk assessment (PRA), is not possible.

Examples of NMSS's successful use of risk information in the past include: the relative risk analysis of the gamma knife; the analysis of the transport of the Trojan reactor vessel; the exemption issued for the TMI-2 fuel debris independent spent fuel storage installation (ISFSI); and the revisions to 10 CFR Parts 35 and 70. These activities were useful in developing experience in the use of multiple forms of risk assessment, as well as in learning the limitations of the methods when used in these arenas. NMSS has a number of activities underway to risk-inform its two arenas of interest -- Materials Safety and Waste Safety -- including the development of an overall framework for risk-informing these arenas to provide a more consistent approach to the use of risk information in our regulatory processes.

In SECY-99-100, "Framework for Risk-informed Regulation in the Office of Nuclear Material Safety and Safeguards," dated March 31, 1999, the U.S. Nuclear Regulatory Commission (NRC) staff proposed a framework for risk-informed regulation in NMSS. In a Staff Requirements Memorandum (SRM), dated June 28, 1999, the Commission approved the staff's proposal, and directed the staff to develop appropriate materials safety goals, analogous to NRC's reactor safety goal, to guide the NRC and to define what safety means for the safety program. Quantitative safety goals developed for nuclear reactors have been used to express the Commission's expectations regarding "how safe is safe enough," and to provide a benchmark for comparing calculated risk measures.

As a first step toward developing a framework, the staff proposed establishing a systematic method to identify and prioritize the candidate regulatory applications that are amenable to expanded use of risk assessment information. This step will be accomplished by applying screening criteria to regulatory application areas as a means to identify the candidate regulatory applications. To be a candidate for expanded use of risk information in NMSS, regulatory application areas must meet the screening criteria.

As part of the staff's effort to use an enhanced public participatory process in developing the framework, the staff held a public workshop in Washington, D.C., on April 25 and 26, 2000.   The staff published draft screening criteria in the *Federal Register* (65 FR 14323, March 16, 2000) announcing the workshop. The purpose of the first part of the workshop was to solicit public comment on the draft screening criteria and their application. The purpose of the second part of the workshop was to solicit public input for the process of developing safety goals for nuclear material applications.

The workshop included participation by representatives from NRC, the U.S. Environmental Protection Agency, the U.S. Department of Energy, the U.S. Occupational Safety and Health Administration, the Organization of Agreement States, the Health Physics Society, the Nuclear Energy Institute, environmental and citizen groups, licensees, and private consultants. A consensus among the workshop participants was that case studies and iterative investigations would be useful to: (1) test the draft screening criteria; (2) show how the application of risk information has affected or could affect a particular area of the regulatory process; and (3) develop safety goal parameters and a first draft of safety goals for each area.

The NMSS staff decided to pursue case studies with the following purposes: (1) to illustrate what has been done and what could be done in NMSS to alter the regulatory approach in a risk-informed manner; and (2) to establish a framework for using a risk-informed approach in NMSS by testing the draft screening criteria, and determining the feasibility of safety goals. Once the screening criteria have been tested using a spectrum of case studies, the criteria can be modified as appropriate, placed in final form, and established as part of the framework for prioritizing the use of risk information in NMSS regulatory applications.

In addition to the overall framework, NMSS is also actively using risk assessment techniques in a number of other specific areas, such as performance assessment in the high-level waste program, the integrated safety assessment for fuel cycle facilities, and hazard barrier analysis in the use of byproduct material. The specific implementation of these activities is further discussed in the following summaries.

Performance Goal: Maintain safety, protection of the environment, and the common defense.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic.

Strategy 1: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-1: Develop a framework for incorporating risk information in the NMSS regulatory process.*

In SECY-99-100, "Framework for Risk-informed Regulation in the Office of Nuclear Material Safety and Safeguards," dated March 31, 1999, the NRC staff proposed a framework for risk-informed regulation in NMSS. In an SRM dated June 28, 1999, the Commission approved the staff's proposal. As a first step toward developing a framework, the staff proposed establishing a systematic method to identify and prioritize candidate regulatory applications that are amenable to expanded use of risk assessment information.

Based on stakeholder input, the NMSS staff decided to pursue case studies with the following purposes: 1) to illustrate what has been done and what could be done in NMSS to alter the regulatory approach in a risk-informed manner; and 2) to establish a framework for using a risk-informed approach in NMSS by testing the draft screening criteria, and determining the feasibility of safety goals. Once the screening criteria have been tested using a spectrum of case studies, the criteria can be modified as appropriate, placed in final form, and established as part of the framework for prioritizing the use of risk information in NMSS regulatory applications.

The case studies will be used to begin the process of developing safety goals for NMSS applications. Specifically, safety goal parameters (e.g., public, worker, acute fatality, latent fatality, injury, property damage, environment damage, safeguards, absolute vs. relative) should be identified in each study. Each case study will determine the feasibility of safety goals in that area, and if feasible, a first draft of safety goals will be developed.

Each case study will be of limited scope, but collectively, the case studies will cover a broad spectrum of NMSS regulatory applications. A case study plan has been developed by the NMSS staff and the NMSS Risk Steering Group. The case studies have been selected in areas we believe would specifically help us to establish a framework, as well as areas that would help to set the groundwork for establishing safety goals. The staff and its contractor will begin working on case studies in October 2000. The staff anticipates working on several case studies simultaneously. When completed, the staff will present the results of the spectrum of case studies to the Commission.

* This implementation activity is also associated with the Nuclear Waste Arena

Additionally, the staff is working with the Office of Human Resources (Technical Training Center) to develop a class to train NMSS staff on risk activities in the materials and waste arenas. The pilot presentation of this class was held September 11-14, 2000. Feedback from the pilot class will be used to create a final version of the class, which will be implemented in December of 2000.

Milestones:

Public meeting to discuss case studies . . . . September 21, 2000 (C)
Deadline for public comments on proposed case studies . . . . October 5, 2000 (C)
Final case study plan . . . . October 2000
Prioritize and schedule case studies;
    issue first statement of work . . . . November 2000
Final version of NMSS risk training class developed;
    implement first class . . . . December 2000

Assignment:

NMSS/RTG

Performance Goal: Maintain safety, protection of the environment, and the common defense.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic.

Strategy 1: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-2: Continue to develop improved risk assessment methods and data for calculating risk in support of risk-informed regulatory decision making.

Work is ongoing to systematically perform a risk analysis of byproduct materials to incorporate risk insights into NMSS regulatory activities, as discussed in SECY-99-100. In SECY-00-0048, "Nuclear Byproduct Material Risk Review," the staff transmitted, to the Commission, NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems," and the staff's approach for use of the technical information. The staff's review of the analysis did not find any areas of regulation or policy needing immediate revision, to address a safety issue. The staff, with contractor support, is conducting an uncertainty analysis of some of the data. However, the staff has used, and will continue to use, the insights gained through the analysis, and will incorporate additional information as it becomes available. In addition to incorporating insights into NMSS risk efforts, the staff plans to use results documented in NUREG/CR-6642 to support the performance goals of the “Planning, Budgeting, and Performance Management” process, and to use the report and its supporting database as resources for evaluating risk issues in byproduct material activities:

a) The staff is currently planning to use the risk information in NUREG/CR-6642 in its analysis of the “Petition for Rulemaking,” PRM-36-1, which requests modification of 10 CFR 36.65(a) and (b). These regulations describe how an irradiator must be attended, to allow for the operation of a panoramic irradiator with qualified operators on site. The staff, with the assistance of a contractor, is conducting an assessment of the Petition with the basis of the models and information found in NUREG/CR-6642, in conjunction with information on historical irradiator accidents worldwide that may have been attributed to the lack of the presence of an onsite operator.

b) The staff plans to use the risk information in NUREG/CR-6642, along with a proposed uncertainty analysis under development, in its review of the “Mallinckrodt Lessons Learned,” and the possible subsequent revision of the Inspection Guidance. NMSS has established two working groups (Phase I and Phase II) to review the materials licensing and inspection program and provide recommendations. Phase I will review findings of the recent Mallinckrodt inspections in Region I and Region III that involved overexposures and to develop lessons learned for licensing and inspection, regulatory changes, and NRC/State jurisdiction. The lessons learned will be categorized as: 1) actions requiring short/long term changes to NRC programs and guidance; 2) actions requiring other regulatory changes (i.e. rulemaking); 3) actions to be considered in Phase II for review of the overall materials program; 4) issues requiring further interactions with other agencies/jurisdictions; and 5) issues to be referred to and considered by the working group on event evaluation. Phase II will review the overall materials program and recommend necessary changes. The scope of the charter will be broad enough to capture events described in our performance measures. The recommendations may include regulatory changes, revisions to the existing licensing and inspection program, and changes to the enforcement policy. The working group will use as a guiding principle the four agency performance goals: maintaining safety; reducing unnecessary regulatory burden; enhancing public confidence; and efficiency, effectiveness, and realism.

Milestones:

a) Visit irradiator sites . . . . October 5, 2000 (C)
Draft risk analysis . . . . October 20, 2000
Final risk analysis . . . . October 29, 2000

b) Phase I working group formed . . . . August 2000 (C)
Final Phase I group report . . . . December 2000
Phase II working group initiated . . . . January 2001
Final Phase II group report . . . . June 2001

Assignment:

NMSS/IMNS and NMSS/RTG

Performance Goal: Maintain safety, protection of the environment, and the common defense.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic.

Strategy 1: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-3: Incorporate risk information into the regulatory framework by revising 10 CFR Part 35, "Medical Use of Byproduct Material."

The Commission has approved the staff's proposal contained in SECY-99-201, which included the proposed revision of 10 CFR Part 35, "Medical Use of Byproduct Material." The revised rule focuses NRC's regulations on those medical procedures that pose the highest risk to workers, patients, and the public, and establishes a risk-informed and more performance-based regulatory structure consistent with NRC's Strategic Plan. The staff used a risk-informed approach to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to health. Risk information that was considered during the development of the rule included events in NRC's Nuclear Materials Event Database; the external review and report by the National Academy of Sciences-Institute of Medicine; a 1993 NRC internal management review and report; the Commission's Strategic Assessment and Rebaselining Project; and comments provided by the stakeholders and the public.

The staff is developing the final rulemaking package for the revision of Part 35, in accordance with the SRM on SECY-99-201, dated February 16, 2000. The Commission approved the rule language and directed the staff to complete the final Part 35 rulemaking package, the associated guidance document, and the revised "Medical Policy Statement." The final "Medical Policy Statement" was published on August 3, 2000 (65 FR 47654). The SRM noted that the rule is risk-informed and significantly reduces the regulatory burden in many areas.

Milestones:

Final rule published . . . . Contingent on Commission SRM
Final NUREG 1556-Vol 9 published . . . . Coincide with final rule publication

Assignment:

NMSS/IMNS/RGB

Performance Goal: Maintain safety, protection of the environment, and the common defense.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic.

Strategy 1: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-4: Incorporate risk information into the regulatory framework by amending Part 70 governing the domestic licensing of special nuclear materials in response to a "Petition for Rulemaking."

On September 18, 2000 (65 FR 56211), the Commission published a final rule (Part 70) that amends its regulations governing the domestic licensing of special nuclear material (SNM) for certain licensees authorized to possess a critical mass of SNM. The Commission's action was in response to a "Petition for Rulemaking," PRM-70-7, submitted by the Nuclear Energy Institute, which was published on November 26, 1996 (61 FR 60057). The rule grants the Nuclear Energy Institute PRM in part, and modifies the petitioner's proposal. The majority of the modifications to Part 70 are included in a new Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material." These modifications were made to increase confidence in the margin of safety at the facilities affected by the rule, while reducing unnecessary regulatory burden, where appropriate.

In developing the rule, the Commission sought to achieve its objectives through a risk-informed and performance-based regulatory approach that had as its primary components: (1) the identification of consequence and likelihood performance requirements for prevention of accidents or mitigation of their consequences; (2) the performance of an integrated safety analysis (ISA) to identify potential accidents at the facility and the items relied on for safety; and (3) the implementation of measures to ensure that the items relied on for safety are available and reliable to perform their functions when needed.

Milestones:

Publish final rule	September 18, 2000 (C)
Publish ISA plan guidance	January 18, 2001
Publish backfit guidance	September 18, 2001
Resolve SRP issues and publish	December 31, 2001
Monitor licensee implementation	Ongoing

Assignment:

NMSS/FCSS

Performance Goal: Maintain safety, protection of the environment, and the common defense.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic.

Strategy 1: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-5: Incorporate risk information into the regulatory framework by integrating insights contained in NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Option for Nuclear Byproduct Material Systems."

The Division of Industrial and Medical Nuclear Safety continued its progress on guidance consolidation, including the integration of risk information, with the final publication of the following NUREG-1556, "Consolidated Guidance about Materials Licensees," volumes:

Vol. 6	"Program-Specific Guidance about 10 CFR Part 36 Irradiators"
Vol. 7	"Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope"
Vol. 11	"Program-Specific Guidance about Licenses of Broad Scope"
Vol. 13	"Program-Specific Guidance about Commercial Radiopharmacy Licenses"
Vol. 14	"Program-Specific Guidance about Well-Logging, Tracer, and Field Flood Study Licenses"

Future revisions will use the insights and information contained in NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems."

Milestones:

First-round revisions published:
Vol. 6 . . . . October 2001
Vol. 7 . . . . December 2002
Vol. 11 . . . . April 2002
Vol. 13 . . . . September 2002

Assignment:

NMSS/IMNS

Performance Goal: Maintain safety, protection of the environment, and the common defense.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic.

Performance Goal: Increase public confidence in NRC regulatory oversight.

Strategy 1: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-6: Work with stakeholders to revise the fuel cycle facility oversight program to increase the use of risk insights for monitoring and for responding to changes in regulated performance commensurate with the impact on risks.

In1999, the staff initiated a revision of the fuel cycle facility safety inspection program as part of the re-inventing government process and consideration of lessons learned from several NRC initiatives for improving regulatory oversight, consistent with SECY-99-100, "Framework for Risk-informed Regulation in the Office of Nuclear Material Safety and Safeguards (NMSS)." The staff's initiative was described in SECY-99-188, "Evaluation and Proposed Revision of the Nuclear Fuel Cycle Facility Safety Inspection Program." A task group comprised of Headquarters and Region staffs is working with stakeholders to develop the revised inspection program. In response to stakeholder comments, the staff broadened the initiative to encompass the entire oversight program for safety and safeguards. The revised oversight program will ensure safety and safeguards are maintained while optimizing regulatory burden. The program will include risk-informed inspections, risk-significance determination, more objective and predictable enforcement and assessment of licensee performance, and enhanced communications with stakeholders. The revised oversight program will build upon the risk-informed regulations associated with the new Part 70 rulemaking, and will focus on the results of licensees' ISAs.

Since beginning the initiative in May 1999, there has been an extensive outreach effort to involve stakeholders in the oversight program revision. Staff conducted seven public workshops with stakeholders to develop the framework and foundation for the revised oversight program, including cornerstones of safety and common defense and security. In this regard, stakeholders and staff have agreed on a foundation and framework for making the fuel cycle oversight program more risk-informed and performance-based. In the most recent public meeting with stakeholders held in September 2000, stakeholders and staff identified the priority and sequence for completing work necessary for the oversight program revision. The staff plans to inform the Commission on the status of the oversight program revision in a paper and briefing in December 2000.

Milestones:

Commission paper on status of oversight program revision . . . . November 28, 2000
Commission briefing on status of oversight program revision . . . . December 20, 2000

Assignment:

NMSS/FCSS

Performance Goal: Maintain safety, protection of the environment, and the common defense.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic.

Strategy 3: *We will confirm that licensees understand and carry out their primary responsibility for conducting activities consistent with the regulatory framework.*

Implementation Activity MS 3-1: Incorporate risk information into the regulatory framework by instituting a risk-informed, performance-based Temporary Instruction for the nuclear medicine program.

SECY-00-0001 and the associated SRM were issued on the staff's proposed medical pilot program (nuclear medicine program) to streamline inspection and enforcement of materials licensees. The approach assesses a licensee's performance relative to desired outcomes. A risk-informed, performance-based Temporary Instruction (TI) for the medical pilot program uses a focus element approach to assess a licensee's performance relative to desired safety-related outcomes. The approach is expected to reduce unnecessary regulatory burden through more efficient and effective inspections.

Milestones:

TI Issuance . . . . April 24, 2000
End of pilot program . . . . One year after issuance date

Assignment:

NMSS/IMNS/RGB

Performance Goal: Make NRC activities and decisions more effective, efficient, and realistic.

Performance Goal: Maintain safety, protection of the environment, and the common defense.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Strategy 1: *We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism.*

Implementation Activity EER 1-1: Develop realistic assessments of risk impacts from radiation exposure.

Risk estimates are derived primarily from health effects at high doses. Regulations are based on a linear hypothesis of radiation protection. This hypothesis assumes that there is a direct relationship between dose and somatic damage and that there is no threshold below which no injury will occur. The regulatory consequence of this assumption is that the Agency's requirements for acceptable radiation exposure limits may be unnecessarily conservative.

Research is examining data on adverse health effects caused by long-term exposure to low levels of radiation and evaluating the realism of current health effects models. Research is also assessing individual and collective doses from materials contaminated with low levels of radioactivity, to support regulatory decisions on the release of such materials from regulatory control.

Milestones:

Complete final report on dose assessment for products and materials exempt from licensing . . . . December 2000

Complete final report on individual doses to support development of the clearance rule . . . . January 2001

Complete report on collective doses to support development of clearance rule . . . . TBD

Provide technical input to guidance on sewer treatment facilities . . . . June 2001

Draft report of JCCRER studies to examine deterministic effects of occupational exposure to radiation . . . . July 2001

Assignment:

RES

Part 2: Risk-Informed Regulation Implementation Activities

Chapter 3. Nuclear Waste Safety Arena

Carl Paperiello, Arena Manager

Performance Goal: Maintain safety, protection of the environment, and the common defense and security.

Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Strategy 1: *We will continue developing a regulatory framework to increase our focus on safety, including the incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-1: Continue to develop improved risk assessment methods and data for calculating risk in support of risk-informed regulatory decision-making by studying spent nuclear fuel cask responses to severe transportation accidents.

On February 17, 2000, the staff sent SECY-00-0042 to the Commission. The paper informs the Commission of the roles of past and present spent nuclear fuel transportation risk studies. SECY-00-0042 discusses NRC's continuing efforts in conducting spent fuel transportation risk studies, the contribution of each to the Commission's transportation safety program, and plans for future communication with the public on spent fuel transport risk.

The staff has completed three transportation risk studies. The first two studies are documented in "Final Environmental Statement on Transportation by Air and Other Modes" (NUREG-0170), and "Shipping Container Response to Severe Accidents" (NUREG/CR-4829). The third study, initiated in 1996, was a reexamination of the risks associated with the shipment of spent reactor fuel by truck and rail. The third study was initiated because: (1) many spent fuel shipments are expected in the future; (2) such shipments will be to facilities along routes and in casks not specifically examined by previous studies; and (3) the risks associated with such shipments can be estimated using new data and improved methods of analysis. The staff completed this reexamination study and published NUREG/CR-6672, "Reexamination of Spent Fuel Shipment Risk Estimates," in March 2000.

A fourth study, referred to as the "Package Performance Study," was initiated in 1999. This study will focus on spent nuclear fuel cask responses to severe transportation accidents. Several public meetings to solicit stakeholder input on the scope of the study have been held, using a public-participation approach. A World Wide Web site has been established to facilitate interactions on the project. Ongoing public interactions throughout this project will help ensure that public concerns are effectively identified and understood.

Milestones:

Evaluate comments on issues report . . . . FY 2001
Revise issues and options report . . . . FY 2001
Identify selected options for testing and analysis . . . . FY 2001
Develop test and analysis plan . . . . FY 2001/2002
Implement test and analysis plan . . . . FY 2002/2004

Assignment:

NMSS/SFPO and RES

Performance Goal: Maintain safety, protection of the environment, and the common defense and security.

Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Strategy 1: *We will continue developing a regulatory framework to increase our focus on safety, including the incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-2: Continue to develop improved risk assessment methods and data for calculating risk in support of risk-informed regulatory decision-making by conducting a spent fuel storage cask probabilistic risk assessment (PRA).

NMSS has initiated a spent fuel dry storage cask PRA in cooperation with the Office of Research (RES). Risk insights from the study will be used to support the staff's decision-making activities and implementing programs involving dry cask storage.

Milestones:

NMSS:
Define project scope . . . . June 2000
Identify accident initiating events . . . . August 2000
Issue draft report on screening analyses . . . . May 2001

RES:
Provide results of dry cask preliminary screening assessment . . . . May 2001
Provide draft report of PRA on dry cask storage . . . . December 2002
Issue report for public comment on dry cask risk assessment . . . . April 2003
Issue final report on dry cask risk assessment . . . . September 2003

Assignment:

NMSS/SFPO and RES

Performance Goal: Maintain safety, protection of the environment, and the common defense and security.

Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Strategy 1: *We will continue developing a regulatory framework to increase our focus on safety, including the incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-3: Incorporate risk information into the regulatory framework in the review of a geologic repository for the disposal of spent nuclear fuel and high-level radioactive waste at Yucca Mountain.

The staff completed and provided the final Yucca Mountain risk-informed, performance-based rulemaking package (Part 63) to the Commission in March 2000. Revision 1 of the Yucca Mountain Review Plan (YMRP) was completed and provided to the Commission in September 2000. The YMRP provides guidance to staff on implementing the risk-informed, performance-based regulations of Part 63, to assure that reviews are risk-informed and the proper level of effort is focused on areas important to the findings.

The staff has prepared and provided comments to the Commission on the U.S. Department of Energy's (DOE's) Draft Environmental Impact Statement for a geologic repository for the disposal of spent nuclear fuel and high-level radioactive waste at Yucca Mountain. The comments should enhance the DOE application for a license for a repository.

Milestones:

Issue Final 10 CFR Part 63 . . . . contingent on Commission SRM
Issue NUREG containing the Yucca Mountain
Review Plan, Rev. 1 . . . . contingent on Commission SRM
Provide staff comments to Commission on DOE's
Site Recommendation Considerations Report . . . . May 2001
Public release of staff comments on DOE's Site
Recommendation Considerations Report . . . . contingent on Commission decision

Assignment:

NMSS/DWM

Performance Goal: Maintain safety, protection of the environment, and the common defense and security.

Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Strategy 1: *We will continue developing a regulatory framework to increase our focus on safety, including the incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-4: Incorporate risk information into the regulatory framework in the analysis of "Geological and Seismological Characteristics for Siting and Design of Dry Cask Independent Spent Fuel Storage Installations," 10 CFR Part 72.

In 1997, the Commission amended 10 CFR Parts 50 and 100 of its regulations to update the criteria used in decisions regarding nuclear power plant (NPP) siting, including geologic, seismic, and earthquake engineering considerations for future NPPs. Part 100 as amended in 1997 placed a new 10 CFR 100.23 section in the regulations to allow the options of using a probabilistic seismic-hazard methodology as part of the geologic and seismic siting criteria. A conforming change to 10 CFR 72.102 is proposed, which will allow new dry-cask ISFSI licensees to take advantage of the Part 100 amendments, specifically Part 100.23. In addition, the proposed rule would provide a risk-informed graded approach to seismic design of ISFSI structures, systems, and components.

Milestones:

Final technical basis . . . . October 2000
Revised rulemaking plan . . . . December 2000
Complete draft regulatory guide . . . . December 2000
Proposed rule package . . . . To be determined
Final rule package . . . . To be determined

Assignment:

NMSS/SFPO

Performance Goal: Maintain safety, protection of the environment, and the common defense and security.

Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Strategy 1: *We will continue developing a regulatory framework to increase our focus on safety, including the incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-5 : Revise regulations applicable to reactors undergoing decommissioning to remove unnecessary burden, and to consider the difference in risk for permanently shutdown reactors compared with operating reactors.

NPPs undergoing decommissioning are subject to many of the same regulations as operating nuclear reactors. Some of the requirements are not justified based on the lower risk presented by a permanently shutdown and defueled reactor, as compared to an operating reactor. The staff has actions underway to make regulatory changes, related to NPP decommissioning, that will reduce the number of licensing actions and exemption requests that need to be submitted by the licensee, and processed by NRC. These changes will be made in a manner that reduces the regulatory burden on licensees commensurate with risk. Further, the staff is considering changes that clarify the requirements to provide predictability, and enhance public confidence based on an increased understanding of what is required during decommissioning. In undertaking these actions, we will maintain the safety of plants undergoing decommissioning by basing the regulatory changes on a technical risk study conducted by the staff.

During a Commission meeting in March of 1999, the Commission directed the staff to determine if a risk-informed methodology could be applied to decommissioning regulations to address the extent to which a zirconium fire needs to be considered for spent fuel storage in the spent fuel pool. In addition, the Commission noted that an integrated approach to decommissioning rulemaking could result in more consistent, predictable regulations. The staff responded with SECY-99-168, dated June 30, 1999, which provided a strategy for decommissioning regulatory improvements. In accordance with the plan outlined in SECY-99-168, the staff has been pursuing three major tasks.

(1) The staff is finalizing a technical study on the risk posed by spent fuel storage in the spent fuel pool of an NPP undergoing decommissioning. A draft report was issued on February 15, 2000. Issuance of a final report is pending, awaiting completion of a response to issues raised by stakeholders and the Advisory Committee on Reactor Safeguards on the draft report.

(2) Based on the results of the spent fuel pool accident risk study, the staff has been developing an integrated rulemaking plan in the regulatory areas of emergency planning; insurance; safeguards; staffing and training; and backfit. On June 28, 2000, the staff provided the integrated rulemaking plan to the Commission (SECY-00-0145). The rulemaking plan is based on risk to the extent provided by the staff’s technical risk study.

However, the rulemaking plan also has prescriptive requirements that lead to regulatory clarity and confidence that are not strictly risk-informed.

(3) The staff is also conducting a broader-based review of decommissioning regulations for NPPs and planning to make further recommendations to the Commission on what additional rulemaking activities may be needed.

The staff will continue to work with stakeholders to identify additional regulatory improvements that can be made for decommissioning NPPs.

Milestones:

Rulemaking plan to Commission (SECY-00-145) . . . . June 2000 (C)
Risk study to Commission . . . . October 2000
Plan for additional decommissioning regulatory improvements . . . . January 2001
Publish proposed integrated rule 2001
Publish final integrated rule 2002
Other decommissioning rulemaking . . . . To be determined

Assignment:

NRR

Performance Goal: Maintain safety, protection of the environment, and the common defense and security.

Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Strategy 1: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed, and where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-6: Incorporate risk information into the review of an independent spent fuel storage installation on the Reservation of the Skull Valley Band of Goshute Indians, within the boundaries of Tooele County, Utah.

The staff has completed the Safety Evaluation Report (SER) for the Private Fuel Storage L.L.C. (PFS) facility, an ISFSI that will be located on the Reservation of the Skull Valley Band of Goshute Indians, within the boundaries of Tooele County, Utah. The PFS facility is designed to store up to 40,000 MTU of spent nuclear fuel in dry storage casks.

The SER includes an examination of potential hazards from the crashes of both civilian and military aircraft flying in the vicinity of the facility. Data connected with aircraft activities at Salt Lake City International Airport, at nearby military facilities, and at nearby municipal airports, were collected and analyzed. Also examined were the potential hazards associated with jettisoned ordnance carried onboard a military aircraft about to crash in Skull Valley. Crash probabilities for aircraft and ordnance were estimated on the basis of several elements that determine the overall likelihood that each specific type of aircraft operation may lead to an impact (or overpressurization) at the proposed facility. These include measures that reflect: traffic density (e.g., flights per year); crash rate (e.g., crashes per mile, crashes per unit area per unit time); and effective target area, as well as specific parameters pertaining to specific aircraft under consideration (e.g., avoidance probability for F-16s, or the probability of on-board live ordnance being present). Other factors, such as human errors in aircraft design, fabrication, or maintenance, were inherently taken into account through the use of historically established crash-rate data.

Based on the information and analysis provided by the applicant, the staff concluded that the cumulative probability of a civilian or military aircraft crashing at, or affecting the facility, is below the threshold probability criterion of 10^{-6} per year. Therefore, there is reasonable assurance that civilian or military air crashes would not pose a hazard to the PFS facility. The staff included these risk insights in the PFS SER, which provides the staff's technical findings to support a future licensing recommendation.

Milestones:

Complete SER . . . . September 2000 (C)
Licensing recommendation to Commission . . . . September 2001

Assignment:

NMSS/SFPO

Performance Goal: Maintain safety, protection of the environment, and the common defense and security.

Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Strategy 1: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed, and where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Implementation Activity MS 1-7: Incorporate risk information into the decommissioning regulatory framework.

In September 2000, the staff finalized the NMSS Decommissioning Standard Review Plan (SRP), which incorporated a risk-informed, iterative approach. This approach will allow staff to evaluate information submitted by a licensee in a timely and efficient manner, and ensure protection of public health and safety. The staff plans to update the SRP in FY2002, based on lessons learned from the application of the SRP to licensing activities during the next 2 years.

NMSS is also reviewing all decommissioning policy and guidance documents for:

> 1) Efficiency, use of a streamlined approach, and user-friendliness of the processes described in the documents; and
>
> 2) The use of risk-informed, performance-based (RIPB) techniques, or risk-informed, less-prescriptive techniques, in the processes described in the documents.

The goal of this activity is to apply RIPB techniques to NMSS' decommissioning process as much as possible. For this, NMSS will use the guidance and experience developed through: (1) the “Business Project Redesign” policy and guidance review and consolidation process for byproduct material licensing (NUREG-1556 series); (2) the experience gained with risk-informing the dose modeling guidance while working on the NMSS Decommissioning SRP (NUREG-1727); and, (3) the ongoing evaluation of new and different approaches to the decommissioning review process that was stipulated in the SRM on decommissioning non-reactor facilities (DSI-9).

Milestones:

Consolidate/update of NMSS decommissioning policy and guidance
- Identify documents for review . . . . December 2000
- Establish criteria for review . . . . March 2001

Issue revision to Decommissioning SRP . . . . FY 2002

Assignment:
NMSS/DWM

Performance Goal: Maintain safety, protection of the environment, and the common defense and security.

Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Strategy 4: *We will keep pace with the national high-level waste management program. We will apply the regulatory framework to pre-licensing reviews and consultations with DOE to resolve the issues most important to repository safety and prepare for addressing a licensing decision within the statutory time period.*

Implementation Activity MS 4-1: Identify those issues most important to repository safety.

The staff will identify those issues most important to repository safety. Staff will accomplish the goal via review of DOE total-system performance assessments, review of supporting documentation, and independent technical analysis. The product of the analysis will be a quantitative and qualitative summary of the issues most important to repository safety.

Milestones:

Issue Consolidated Issue Resolution Status Report . . . . September 2001

Assignment:

NMSS/DWM

Performance Goal: Maintain safety, protection of the environment, and the common defense and security.

Performance Goal: Make the NRC activities and decisions more effective, efficient, and realistic.

Performance Goal: Reduce unnecessary regulatory burden on stakeholders.

Strategy 4: *We will keep pace with the national high-level waste management program. We will apply the regulatory framework to pre-licensing reviews and consultations with DOE to resolve the issues most important to repository safety and prepare for addressing a licensing decision within the statutory time period.*

Implementation Activity MS 4-2: Resolve key technical issues identified as being greater contributors to risk.

The issues identified through Strategy 4, Implementation Activity 1, will be supplied to staff involved in pre-licensing reviews and consultations with DOE to focus effort on resolving issues most important to repository safety. All key technical issues previously identified in the high-level waste project will receive adequate review to ensure safety and protection of the environment. However, key technical issues identified as being greater contributors to risk in Strategy 4, Implementation Activity 1, will receive a more thorough evaluation of: (1) data and model justification; (2) data uncertainty; (3) model uncertainty; (4) model support; and (5) integration.

Milestones:

Conduct public meetings with DOE on regulatory
technical issues and paths to closure . . . . March 2001
Issue Consolidated Issue Resolution Status Report . . . . September 2001

Assignment:

NMSS/DWM

Appendix: Considerations for Implementing a Risk-Informed Regulatory Framework

As the agency moves forward toward risk-informed regulation, certain fundamental approaches to safety will continue to shape the agency's decisions. Four of these fundamental principles are defense-in-depth, the use of safety margins to account for uncertainty, the principle of "as low as reasonably achievable" (ALARA) in radiation protection, and the use of safety goals. Important considerations which need to be addressed in utilizing these approaches are discussed below. These are followed by some additional guidance concerning the concept of regulatory analysis and performance-based implementation. The purpose of the discussion in this Appendix is to help ensure a uniform set of considerations is factored into all agency risk-informed initiatives.

I. Defense in Depth

Defense-in-depth is an element of the NRC's safety philosophy that employs successive compensatory measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. Risk information is used to decide whether event frequency hazard consequences warrant defense-in-depth and to suggest appropriate defenses. Defense-in-depth is a philosophy used by the NRC to provide redundancy for facilities with "active" safety systems, as well as the philosophy of a multiple-barrier approach against fission product releases. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges.

The concept of defense in depth has always been and will continue to be a fundamental tenet of regulatory practice in the nuclear field. It is expected that defense in depth for reactors and nuclear materials (which includes activities involving disposal, transportation and storage, processing and fabrication, and industrial and medical applications) may need to be considered differently due to the greater diversity in materials licensed activities and to the differences in safety issues.

In its May 25, 2000 letter to Chairman Meserve, the Advisory Committee on Nuclear Waste (ACNW) provides a perspective on the role of defense-in-depth in risk-informed regulation. "The primary need for improving the implementation of defense in depth in a risk-informed regulatory system is guidance to determine how many compensatory measures are appropriate and how good these should be. To address this need, we believe that the following guiding principles are important:

- Defense in depth is invoked primarily as a strategy to ensure public safety given the unquantified uncertainty in risk assessments. The nature and extent of compensatory measures should be related, in part, to the degree of uncertainty.
- The nature and extent of compensatory measures should depend on the degree of risk posed by the licensed activity
- How good each compensatory measure should be is, to a large extent, a value judgement and, thus, a matter of policy."

The ACNW letter further states that in the reactor arena, defense in depth entailed “placing compensatory measures on important safety cornerstones to satisfy acceptance criteria for defined design-basis accidents that represent the range of important accident sequences.” For the reactor arena, Regulatory Guide 1.174 states that consistency with the defense-in-depth philosophy will be preserved by ensuring that:

- a reasonable balance is preserved among prevention of accidents, prevention of barrier failure, and consequence mitigation,
- an over-reliance on programmatic activities to compensate for weaknesses in equipment or device design is avoided,
- system redundancy, independence, adversity are preserved commensurate with the expected frequency, consequences of challenges to the system, and uncertainties (e.g., no risk outliers),
- the independence of barriers is not degraded such that defenses against potential common cause failures of multiple barriers are preserved, and the potential for the introduction of new common cause failure mechanisms is assessed,
- defenses against human errors are preserved, and
- the intent of the fundamental design features is maintained.

The Advisory Committee on Reactor Safeguards (ACRS) has expressed concerns about the role that defense in depth should have in a risk-informed regulatory scheme. The Committee cites instances in which “seemingly arbitrary appeals to defense in depth have been used to avoid making changes in regulations or regulatory practices that seemed appropriate in the light of results of quantitative risk analyses.” The letter’s attachment describes two models on the scope and nature of defense in depth. “In the structuralist model, defense in depth is primary, with PRA available to measure how well it has been achieved.” (This is the model implicit in the agency’s PRA Policy Statement and in Regulatory Guide 1.174 concerning risk-informed changes to reactor licensing bases.) In the rationalist model, “the purpose of defense in depth is to increase the degree of confidence in the results of the PRA or other analyses supporting the conclusion that adequate safety has been achieved. ...What distinguishes the rationalist model from the structural model is the degree to which it depends on establishing quantitative acceptance criteria, and then carrying formal analyses, including analysis of uncertainties, as far as the analytical methodology permits.” To define the role of defense in depth in risk-informed regulation and to establish a consistent and reasoned approach, the following considerations should be addressed:

- What elements of defense in depth should be independent of risk information; e.g.,
    - provide prevention and mitigation protection?
    - use of good engineering practices (e.g., codes and standards)?
    - number and nature of barriers to radiation release?
    - emergency plans and procedures?

Risk insights can make the elements of defense in depth more clear by quantifying them to the extent practicable. Although the uncertainties associated with the degree of protection provided by some elements of defense may be substantial, the fact that these elements and uncertainties have been quantified can aid in determining how much defense makes regulatory sense. Decisions on the adequacy of or the necessity for elements of defense should reflect risk insights gained through assessment of the hazard and identification of the individual performance of each defense system in relation to overall performance.

- What elements of defense in depth should be dependent upon risk information; e.g.,
  - the balance between prevention and mitigation?
  - the number of barriers?
  - the need for redundancy, diversity, independence of systems?
  - the events that need to be considered in the design?
- Do the defense-in-depth considerations expressed in Regulatory Guide 1.174 apply?

II. Safety Margins

Existing regulations were developed to ensure that adequate safety margins exist to account for uncertainties in analysis and data. In the reactor arena, Regulatory Guide 1.174 states that acceptable risk-informed changes to a nuclear power reactor's licensing basis will be consistent with the principle that sufficient safety margins are maintained. Improved information from data analysis, research experiments, and the like suggest that excessive safety margins exist given the current state of knowledge and current uncertainties. As regulations in the reactor, materials, and waste arenas are evaluated to improve the focus on safety, regulations that foster excessive safety margins will be candidates for change. To define the role that safety margins play in risk-informed regulation and to establish a consistent and reasoned approach, the following considerations should be addressed:

- How should safety margins be weighed in the context of the radiological hazard?
- How should safety margins be employed to account for uncertainties in engineering analysis:
  - realistic analysis with conservative acceptance criteria?
  - specified confidence level?
  - role of codes and standards (i.e., do they inherently address safety margin)?
- How should safety margins be employed to account for uncertainty in risk:
  - parameter uncertainty – defense in depth (i.e., redundancy, diversity, independence)?
  - incompleteness in risk analysis (e.g., engineering judgment)?
  - model uncertainty (e.g., conservative acceptance criteria)?

III. Radiation Protection and the Principle of "As Low As Reasonably Achievable" (ALARA)

The 1972 report of the Advisory Committee on the Biological Effects of Ionizing Radiations (BEIR) contended that, in the absence of better data, there was no reasonable alternative to a linear hypothesis of radiation protection. The linear hypothesis assumes a straight-line correlation between dose and somatic damage and does not allow for a threshold below which no injury will occur. Indeed, the linear hypothesis might overestimate the risks by failing to account for the effects of dose rate and cell repair. The 1990 BEIR-V report reaffirmed that a linear, no-threshold model of cancer risk (other than leukemia) was most consistent with the data. Consequently, licensees are expected to keep radiation releases to a level as low as reasonably achievable. In keeping with this philosophy of "as low as reasonably achievable," the staff seeks to strike a balance that considers the capabilities of technology and the costs of equipment while providing ample protection to the public. That is, the staff takes into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations in relation to the utilization of atomic energy in the public interest".

IV. Safety Goals

Certain high-level considerations concerning quantitative safety goals need to be addressed in making decisions with respect to the approach and direction of risk-informed changes. First, and most fundamental, is the issue of whether or not a safety goal needs to be established to guide risk-informed changes. In general, a safety goal is useful to define the desired level of safety. In the reactor arena, safety goals were established to define "how safe is safe enough" or, in other words, when additional regulation is not warranted. It is expected that if safety goals (that go beyond adequate protection) are defined for other regulated activities, they would be used in a similar capacity. Currently, there are no explicit safety goals in the Nuclear Materials Safety and Nuclear Waste Safety arenas. The staff is pursuing the review of selected case studies to determine the feasibility and efficacy of safety goals in these arenas.

Notwithstanding questions concerning the need, several issues need to be considered if goals are developed. These issues are relevant across the full spectrum of regulatory applications and can be posed as the following questions:

- What are the risks that the goal will limit? (i.e., early fatalities, latent fatalities, illness, individual risk, societal risk, economic risk, environmental risk)
- What is an acceptable level of risk?
  - some fraction of other risk (i.e., relative risk)?
  - a consequence-based limit (i.e., an absolute risk)?
  - dependent on nature of population?
- Who are the populations at risk?
  - public (specified by proximity, biological vulnerability, current and future generations, etc.)?
  - workers
  - both of these?
- Are the predominant risks from normal operations or accidents or both?
- Over what time frame does the goal apply (e.g., years vs. centuries)?
- What metrics best express the goal?

Once a safety goal is determined, its implementation needs to be considered. Questions regarding implementation include:

- What is the role and relationship of the traditional principles of defense-in-depth, safety margins, and ALARA to the goals and risk-informed regulation?
- What is the role of cost-benefit in implementing the goals?
- What is the nature of the risk assessment needed to measure against the goals?
- How should uncertainties be considered in establishing goals?

As alluded to earlier, a risk-informed approach to regulation can be taken without establishing safety goals. One such approach is to assess relative changes in risk as a result of postulated changes to current regulatory requirements. If an approach such as this is taken, there are additional implementation issues which need to be considered, such as:

- What metrics should be used to measure changes in risk?
- What increases in risk are acceptable?
- What is the role of cost-benefit is identifying and assessing risk-informed regulatory changes?

In its activities that are described in Part 2 of this plan, the staff will address the issue of establishing safety goals beyond those already established.

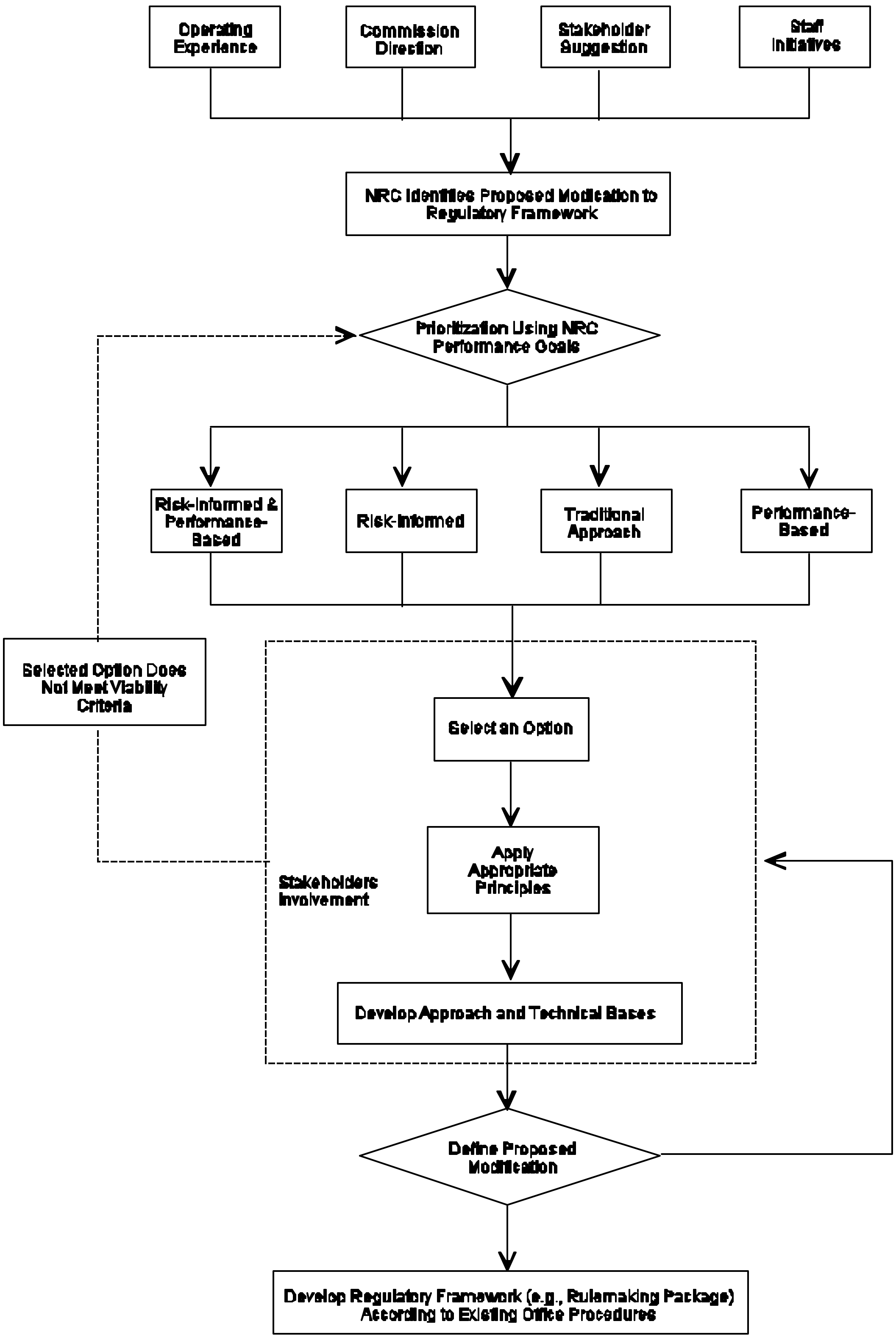
V. Regulatory Analysis

The NRC performs regulatory analyses to support numerous NRC actions affecting reactor and materials licensees. In general, each NRC office ensures that all mechanisms used by the staff to establish or communicate generic requirements, guidance, requests, or staff positions that would affect a change in the use of resources by its licensees, include an accompanying regulatory analysis. In regard to relaxation of requirements, NUREG/BR-0058 states that a regulatory analysis should provide that level of assessment that will demonstrate with sufficient reasonableness that the two following conditions are satisfied:

- The public health and safety and the common defense and security would continue to be adequately protected if the proposed reduction in requirements or positions were implemented
- The cost savings attributed to the action would be substantial enough to justify taking the action

As part of the staff's activities, the role of regulatory analysis in evaluation risk-informed regulatory changes will be established to ensure a consistent and predictable regulatory framework.

VI. Performance-Based Implementation The agency has defined a performance-based requirement as one that "relies upon measurable (or calculable) outcomes (i.e., performance results) to be met, while providing flexibility to the licensee as to the means of meeting these outcomes. A performance-based regulatory approach is one that establishes performance and results as the primary basis for regulatory decision making. To the extent appropriate, risk-informed regulation should incorporate performance-based regulation in that, if risk-informed changes are to be made, they should be made in a performance-based fashion whenever possible. The corollary is also true; performance-based regulations should be risk-informed when possible. Figure 1 illustrates that both risk-informed and performance-based approaches will be pursued as appropriate when modifying the regulatory framework.


Operating Experience
Commission Direction
Stakeholder Suggestion
Staff Initiatives
NRC Identifies Proposed Modication to Regulatory Framework
Prioritization Using NRC Performance Goals
Risk-Informed & Performance-Based
Risk-Informed
Traditional Approach
Performance-Based
Selected Option Does Not Meet Viability Criteria
Select an Option
Apply Appropriate Principles
Stakeholders Involvement
Develop Approach and Technical Bases
Define Proposed Modification
Develop Regulatory Framework (e.g., Rulemaking Package) According to Existing Office Procedures

Part 3: Corporate Management Strategies

Chapter 1. Staff Training to Support Implementation of Risk-Informed Regulation

Kenneth Raglin, Manager

Overview

The NRC staff uses probabilistic risk assessment (PRA) and risk management as important elements of its licensing and regulatory processes. As the agency shifts to greater use of and reliance on PRA methods and risk-informed regulation, all technical staff members, including inspectors, will need to develop an understanding of the strengths and limitations of PRA and other risk methods and their use. In 1994, the Commission endorsed the PRA Implementation Plan to as a means of achieving the concepts in the PRA policy statement. To support the goal of improved regulatory activities through increased use of PRA technology, the plan included an extensive training program. Training of the staff is a critical part of the change in the regulatory culture of the agency.

Three levels of PRA users were identified and a PRA curriculum was developed. The first broad category of PRA user is the Basic User. This category consists of staff who use PRA results and require some basic information on how PRAs are performed and the results are obtained. The second category is called the Advanced User and consists of staff who work with PRA models or manage contractor efforts with PRA models. The Advanced User will require more extensive training. The final category is the Expert Practitioner. This group consists of staff who perform quality assurance and expert advisory functions as well as develop new PRA models.

PRA Training Program

The PRA training program is designed to assist staff members to develop new knowledge, skills, and abilities (KSAs) in PRA methods and statistics. The current PRA curriculum is described in NUREG/BR-0228 “Guidance for Professional Development of NRC Staff in Regulatory Risk Analysis.” This document provides a summary of suggested training programs recommended for Nuclear Regulatory Commission personnel who either perform or use the results of probabilistic risk assessments (PRAs) in their day-to-day work activities. Tasks range from using PRA results to working with PRA models. This document is designed to allow the formulation of training programs based on job requirements, educational background, and PRA experience.

As the level of KSAs move from Basic User to Advanced User to Expert Practitioner, less information can be gained in short training courses, and greater emphasis must be placed on formal education and experience. Consequently, the PRA curriculum courses emphasize KSAs to meet the needs of Basic and Advanced Users. Placement of NRC technical staff positions into one of the three KSA categories is the responsibility of NRC line management. NUREG/BR-0228 provides recommendations for this placement and recommended course sequences.

The current curriculum consists of 13 courses: Probability and Statistics for PRA, PRA Basics for Regulatory Applications, PRA Insights into IPEs, PRA for Technical Managers, PRA Technology and Regulatory Perspectives, System Modeling Techniques for PRA, SAPHIRE Basics, Advanced SAPHIRE, Human Reliability Assessment, External Events, Accident Progression Analysis, Accident Consequence Analysis, and Risk Assessment In Event Evaluation. Descriptions of these course can be found in the Technical Training Center's on-line course catalog.

From FY 1995 through FY 2000, some 1976 students have attended PRA curriculum courses; an average of 329 students a year. Attendance peaked in FY 1998 with 507 students. 545 students have attended the PRA Basics for Regulatory Applications course, 272 have attended the PRA for Technical Managers course since its creation in 1997 and 255 students have attended the PRA Technology and Regulatory Perspectives course since its inception in1998.

Current Initiatives

The current curriculum has evolved to meet staff needs and has been revised as the agency's use of risk insights has matured. The PRA Technology and Regulatory Perspectives course, for example, is the basic course required for all reactor inspector personnel. The course content has been revised and is currently undergoing further review to specifically support the needs of the Reactor Oversight Process. Future revisions will further emphasize the theory, basis, and utilization of the probabilistic-based Significance Determination Process. The course workshops are being redesigned to provide an opportunity for students to utilize established guidance and tools of the Reactor Oversight Process to plan an inspection and evaluate the significance of inspection findings using the SDP.   Target date for completion of the course revisions is March 2001. The course has met a critical need during the transition to risk-informed regulation.

The curriculum is also expanding to support NMSS' move to risk-informing its programs. NMSS is developing a three tier approach to staff training. Tier 1 courses would be aimed at managers and supervisors, Tier 2 courses at NMSS technical staff and Tier 3 courses at risk analysts and specialists. Development of the first Tier 2 course is underway. A higher level version of that course will become the first Tier 1 course. Tier 3 courses will likely utilize the agency's Form 368 process for external training.

The working title of the first course is "Introduction to Risk Assessment in NMSS." The course is being developed through HR's PRA training agreement with Idaho National Engineering and Environmental Laboratory (INEEL). The purpose of the course is to provide students with an understanding of:

- Why risk concepts are used in the NRC
- What risk methods are being used, and what students should know about these risk concepts, and
- How the risk concepts are applied, and how the application of risk concepts influences regulatory decision making.

Course topics include:

1. Introduction - NRC Policy on the Use of Risk Information

2. Framework for Risk-Informed Regulation in NMSS

3. Risk Concepts and Methodology

4. Application of Risk Insights to Regulatory Decision Making Activities (Case Studies)

5. Risk Communication

Detailed course objectives have also been developed. Course development started in June, 2000 and the course was successfully piloted the week of September 11, 2000. However, significant work remains before the course is ready for implementation. The current goal is to make the first presentation in December, 2000. Five presentations are planned for FY 2001. Current projections call for approximately 400 headquarters and regional staff to attend the training.

NRR has formed a Working Group on Improving Risk Expertise. The working group is considering two main issues: (1) options for improving probabilistic-based SDP understanding and use and (2) expanding the number of individuals capable of utilizing NRC PRA software tools to perform and interpret basic quantitative risk analysis, and who can (through work experiences) develop a skill set useful for the review of more advanced risk analyses. These individuals would assist the Senior Reactor Analyst's (SRA's) review of issues arising from the probabilistic-based SDPs. The working group is also reviewing improvements in SRA training and qualification. Development of an IMC 1245 standard qualification criteria for SRA certification is being considered along with ways to shorten the time required to qualify as an SRA. These might include shorter SRA rotations and identification of efficiencies in the SRA training course series.

NUREG/BR-0228 "Guidance for Professional Development of NRC Staff in Regulatory Risk Analysis" will also be updated as the new NMSS curriculum is refined and revisions to the SRA qualification program are identified.

Part 3: Corporate Management Strategies

Chapter 2. Internal Communication Activities

Ashok C. Thadani, RIRIP Manager

Risk-informed regulation entails change both in the regulations and in how the NRC staff carries out its tasks. The January 2000 GAO report provides results of a survey that solicited staff opinions concerning risk-informed regulation. It is clear from the reported results that the staff of the NRC is highly motivated to maintain safety. Concerns were expressed that illustrated uncertainty about how risk-informed regulation may effect safety. Thus, it is important that a plan be implemented to ensure effective internal communications with regard to risk-informed regulation. The SRM dated April 18, 2000 concerning the RIRIP addressed this issue. “Management should continue its efforts to communicate effectively with the staff on the implementation of risk-informed regulatory initiatives, and should ensure that mechanisms exist to solicit and consider staff input and feedback on the agency’s plans and progress on these initiatives.” The SRM went on to direct the staff to describe an internal communications plan and training requirements for the staff in the October 2000 update of the RIRIP.

Communication Goals

The goals of this communication plan are:

1. To create and foster awareness of the RIRIP.
2. To communicate the planned activities, major milestones, and status of implementation activities to NRC staff.
3. To establish mechanisms to solicit and consider staff input and feedback on the agency’s plans described in the RIRIP.

Audiences

Although it is indeed vital to communicate effectively with external stakeholders, the primary focus of this communication plan is:

1. NRC staff in Headquarters and the Regions
2. The Commission
3. The Executive Director for Operations, the Chief Financial Officer, the Chief Information Officer.

Communication Mechanisms

MECHANISM	PURPOSE
Yellow Announcement	Alert the staff to the availability of the RIRIP and solicit input and feedback
Website	Give the staff ready access to the RIRIP and provide a mechanism for providing input and feedback
In-house meetings - staff - management	Conducted by NRC management to provide a forum for discussion
Training	Discussed in Chapter 1 of Part 3

Messages to Communicate

1. What is risk-informed regulation?
2. Safety comes first.
3. Change is necessary.
4. The RIRIP provides the agency's plans for moving forward with risk-informed regulation.
5. Staff input and feedback on the agency's plan and on its progress toward risk-informed regulation will be solicited, are welcome, and will be considered in updates to the RIRIP.
6. Some major implementation activities (e.g., those associated with the reactor oversight process) have communication plans specifically tailored to those activities.

Schedule of Communication Activities

Provide RIRIP to the Commission	October 2000
Brief ACRS	November 2000
Brief ACNW	TBD
Issue Yellow Announcement on availability of RIRIP	December 2000
Add RIRIP to NRC Website	February 2001
In-house meetings	TBD
Provide next RIRIP update to the Commission	May 2001

Consideration of Input and Feedback

Input and feedback received from the staff will be summarized and discussed at inter-office meetings held as part of the effort to provide semi-annual updates of the RIRIP as well as at meetings of the PRA Steering Committee. This input and feedback will be assessed to determine appropriate changes to the agency's planned implementation activities.

Guiding Communication Principles

Some general guidance is provided to ensure the development of effective communication plans. In general, the communications activities should:

- Clearly delineate the purpose and results expected from moving to a risk-informed approach
  - Define the goals and milestones of the RIRIP or specific implementation activity
  - Define the stakeholder groups that are critical to implementing risk-informed regulation (e.g., the Commission, the EDO, the regulated industry, Agreement States, public interest groups, the public)
  - Clarify the role of stakeholders in the process and why their involvement is critical to success
- Develop an integrated communication plan
  - Define the purpose of communication or results expected
  - Identify the targeted audience
  - Develop the messages
  - Select the messengers
  - Select modes of communications, including where two-way feedback is critical
  - Adopt an integrated approach to communications across the three arenas (i.e., reactor safety arena, nuclear materials safety, and nuclear waste safety)
- Develop measures for success of communication